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TRIALS SEARCH GUIDE

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HIV Clinical Trials in California

Compiled by the Community Consortium

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Introduction

Clinical trials are often the first place people with HIV can gain access to promising new medical treatments. They are an important option for anyone with HIV. Unfortunately, learning about clinical trials can be difficult and confusing. That's where *Trials Search* and this *Guide* can help.

Trials Search is a database of open HIV clinical trials in the United States. *Trials Search* matches clinical trial entry requirements with an individual's medical history and current health status and produces a personalized list of studies for which he or she might qualify. *Trials Search* is a free service. Call (800) 492-5777 for more information or to receive a questionnaire.

The *Guide* includes information about all clinical trials of which we are aware that are currently enrolling patients in California. No endorsement is made of any trial described herein. Every reasonable effort has been made to ensure that the information presented in the *Guide* is accurate, comprehensive and up-to-date. However, eligibility and other criteria are subject to change, and trials may close to patient enrollment at any time.

The Community Consortium welcomes information about all clinical trials available throughout the United States for inclusion in *Trials Search*. Any trial which has been reviewed and approved by an Institutional Review Board may be included. Institutional Review Boards are committees which are set up to review research involving human subjects to ensure that studies are ethical and scientifically sound. Anyone with information appropriate for publication is asked to call the Consortium at (415) 476-5777 or (800) 492-5777.

Trials Search and the database HIV Clinical Trials in the United States are also available on the Internet at:

http://hivinsite.ucsf.edu/tsearch

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Trials search guide.

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Research staff at more than 60 trial sites who furnished the bulk of the information contained in the Guide. This project would not have been possible without their considerable expertise and generous contribution of time and energy.

The following publications for their reliability and usefulness:

- *AIDS/HIV Treatment Directory* published by the American Foundation for AIDS Research (AmFAR).
- *Bulletin of Experimental Treatments for AIDS (BETA),* from the San Francisco AIDS Foundation.
- *Treatment Issues* from the Gay Men's Health Crisis (GMHC) for the Glossary of Medical Terms which is a reference and basis for some of our glossary entries. The online Guide uses the GMHC Glossary as a whole.

An Association of Bay Area
HIV Health Care Providers

The Community Consortium is affiliated with the
UCSF AIDS Program at San Francisco General Hospital.

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New

1. HIV Infection: Invirase

Title:

NV15355C: A Randomized, Parallel Arm, Comparative, Open-Label, Multicenter Study of the Activity and Safety of Two Formulations of Saquinavir in Combination with Two Nucleoside Antiretroviral Drugs in Treatment Naive Patients

Type of treatment:

Invirase: antiretroviral, protease inhibitor

Purpose:

To learn about the safety and effectiveness of two formulations of saquinavir when combined with two licensed nucleoside antiretroviral drugs in patients who have never had any treatment for their HIV disease.

About the study:

Patients are assigned by chance to receive either soft gelatin or hard gelatin capsules of saquinavir to take in addition to two licensed antiretroviral drugs which the patient has not taken for more than four weeks within one month of study entry. Patients will know which saquinavir formula they are taking. After 16 weeks, all patients will receive soft gelatin saquinavir. Study visits are every four weeks for the first four months and every two months until week 48. The study lasts about two years.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 5,000 copies
- HIV positive
- At least 13 years old

Not allowed:

- Current or past use of any protease inhibitors
- More than four weeks of treatment with any licensed nucleoside antiretroviral drug up to one month before screening
- Current AIDS-related opportunistic infections

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, ext. 3763

UC Davis Medical Center
Bill Lippert, MBA
(916) 734-8475

New

2. HIV Infection: GM-CSF

Title:

001.0012: A Phase III Randomized, Double-Blinded, Placebo-Controlled Trial of Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor (rhu GM-CSF in Patients With Advanced HIV Disease

Type of treatment:

GM-CSF: white blood cell stimulator

Purpose:

To see if GM-CSF (Leukine) can reduce the number of new or recurring AIDS-related infections over time.

About the study:

Patients are assigned by chance to receive injections of GM-CSF or placebo. GM-CSF and its placebo are given as injections into a muscle. Patients will be taught how to give themselves injections. Neither patients nor their doctors will know which they are receiving until the study ends. Injections are given three times a week. There is one screening visit and there will be eight study visits during the 24-week treatment period. The study lasts 24 weeks with the possibility of a 24-week extension.

Required:

- CD4 cell (T-cell) range: 50 or less. Patients with a history of a previous AIDS-defining opportunistic infection may have 100 or less
- Viral load range: not applicable
- HIV positive
- At least 16 years old
- Patients must be on stable antiretroviral therapy for at least four weeks prior to study entry

Not allowed:

- Use of other investigational immunomodulators or cytokines, other than erythropoietin
- Any radiation or chemotherapy within two weeks prior to study entry OR the need for such during the study

Location:

AIDS Community Research Consortium
Brenda Cayme, RN
(415) 364-6563

Davies Medical Center HIV Institute
Trisha Harasty
(415) 565-6222

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

New

3. HIV Infection: Indinavir

Title:

CPCRA 041: A Randomized Trial of Immediate Versus Deferred Indinavir (IDV) in Addition to Backround Antiretroviral Therapy in HIV-Infected Patients With CD4+ Cell Counts Between 200 and 500/mm³ and Plasma HIV RNA Levels of 10,000 Copies/mL or More

Type of treatment:

Indinavir: antiretroviral, protease inhibitor

Purpose:

To see what effect taking indinavir in addition to other antiretroviral therapy has on disease progression.

About the study:

Patients are assigned by chance to receive indinavir (also called Crixivan) or placebo to take in addition to their antiretroviral medications. Neither patients nor their doctors will know which they are taking. Study visits are every four months and patients will have CD4 (T-cell) counts and viral load counts done. The results of these tests will determine the course of treatment. If a patient experiences a disease progression event, they will be offered open-label (real) indinavir. Patients should be able and willing to change their antiretroviral therapy in accordance with study requirements and/or at the discretion of their physician. Patients will be on this study indefinitely.

Required:

- CD4 cell (T-cell) range: between 200 and 500
- Viral load range: at least 10,000 copies
- HIV positive
- At least 16 years old

Not allowed:

- Use of invirase (saquinavir) for more than 14 days
- Use of any protease inhibitor other than saquinavir
- Any past serious opportunistic infection
- Fever of 101.3 F or greater within three days of study entry
- Use of NNRTIs, such as delavirdine or nevirapine during the study
- Women who are pregnant or breastfeeding

Location:

Community Consortium
To be arranged through physician-see page 105
(415) 476-9554

New

4. HIV Infection: bis-POM PMEA (2)

Title:

CPCRA 039: A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Adefovir Dipivoxil (bis-POM PMEA) in Prolonging Survival of HIV-Infected Individuals With a CD4+ Cell Count of 100/mm³ or Less

Type of treatment:

bis-POM PMEA: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if bis-POM PMEA is safe and effective in prolonging survival of patients with advanced HIV disease. To see if bis-POM PMEA is effective in preventing the development of CMV end-organ disease in patients with advanced HIV disease who are also infected with CMV.

About the study:

Patients are assigned by chance to receive bis-POM PMEA or placebo. Neither patients nor their doctors will know which they are taking until the study ends. Both bis-POM PMEA and its placebo are pills and taken once a day. Patients will also take one pill per day of a supplement called L-carnitine. For the first 400 patients to enroll nationally, study visits will be two weeks after the baseline visit, then every month for six months, then every other month until month 12. After 12 months, study visits will be every four months. Patients who enroll after the first 400 will have study visits at month 1, month 2, month 4, then every four months. Patients will be on this study at least 20 months.

Required:

- CD4 cell (T-cell) range: 100 or less
- Viral load range: not applicable
- HIV positive
- At least 13 years old

Not allowed:

- Past or current CMV organ disease, such as retinitis or colitis
- Women who are pregnant or breastfeeding
- Use of foscarnet within 60 days of study entry
- Use of any of the following within two weeks of study entry; acyclovir (more than 1 gram/day), cidofovir, famciclovir, ganciclovir, 123W94, ISIS 2922, lobucavir, MSL109, valaciclovir
- Any condition that would require the use of the above-mentioned medications

Location:

Community Consortium
To be arranged through physician-see page 105
(415) 476-9554

New

5. HIV Infection: Nelfinavir, Ritonavir

Title:

CPCRA 042: A Randomized Trial of the Efficacy and Safety of Nelfinavir Versus Ritonavir Added to Backround Antiretroviral Nucleoside Therapy in HIV-Infected Individuals With CD4+ Cell Counts of 100/mm^3 or Less

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To compare nelfinavir to ritonavir when added to backround antiretroviral therapy in terms of delaying disease progression and to measure safety.

About the study:

Patients are assigned by chance to receive nelfinavir or ritonavir to take with their antiretroviral therapy. Patients who are not taking any antiretroviral therapy are eligible to join, although the use of protease inhibitors by themselves is not recommended unless there is no other alternative. Patients will be allowed to switch to the other protease inhibitor if they experience disease progression or cannot tolerate their assigned medication. Both nelfinavir and ritonavir are pills and taken by mouth. There will be a one-month study visit after the screening visit, then every four months thereafter. The study lasts at least 18 months.

Required:

- CD4 cell (T-cell) range: 100 or less
- Viral load range: not applicable
- HIV positive
- At least 13 years old

Not allowed:

- Prior use of any protease inhibitors other than saquinavir
- Severe AIDS dementia complex
- Women who are pregnant or breastfeeding
- Use of protease inhibitors during the study

Location:

Community Consortium
To be arranged through physician-see page 105
(415) 476-9554

New

6. HIV Infection: Indinavir, AZT, 3TC (2)

Title:

MK-054: Multicenter, Open-Label, Randomized, 36-Week Pilot Study to Compare the Safety and Activity of Indinavir Sulfate, 800 mg q8h vs 1000 mg q12h vs 1200 mg q12h in Combination with Zidovudine and 3TC

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To compare different doses of indinavir (Crixivan) for safety and antiviral activity when combined with AZT and 3TC.

About the study:

Patients are assigned by chance to receive one of three doses of indinavir to take with AZT and 3TC. Patients will know which dose they are taking. Indinavir, AZT and 3TC are pills and taken by mouth. This study will last 36 weeks.

Required:

- CD4 cell (T-cell) range: between 150 and 500
- Viral load range: at least 10,000 copies
- HIV positive
- At least 18 years old
- Must have taken AZT for at least 16 weeks

Not allowed:

- Prior use of 3TC or any protease inhibitors
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center
Irene Teran, RN
(213) 343-8285

New

7. HIV Infection: Indinavir, AZT, 3TC (3)

Title:

ACTG 343: A Prospective Randomized Double-Blind Trial of Three Maintenance Regimens for HIV Infected Patients Receiving Induction Therapy with Zidovudine, Lamivudine, and Indinavir

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To find out which drugs can keep the amount of HIV virus in the blood as low as possible.

About the study:

All patients will receive AZT, 3TC and indinavir (a protease inhibitor) for six

months. Then, patients whose HIV virus cannot be detected will be assigned by chance to continue to take either AZT + 3TC + indinavir, AZT + 3TC, or indinavir alone for 12 months. Every six months, some patients whose HIV virus still cannot be detected will be assigned by chance to continue taking these drugs or to stop taking the drugs. Study visits are once a month. The entire study lasts three years.

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: 1,000 copies or more
- HIV positive
- At least 18 years old

Not allowed:

- Any acute infections within 14 days of study entry
- Any cancer requiring chemotherapy
- Hepatitis within 30 days of study entry
- Severe peripheral neuropathy
- Prior treatment with 3TC or 1592U89
- More than two weeks use of any protease inhibitor or any use within 14 days of study entry
- Use of any interleukins, interferons, GM-CSF or vaccines within 30 days of study entry
- Women who are pregnant or breastfeeding

Location:

Harbor-UCLA Medical Center
Sally Kruger
(310) 222-3848

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

UCSF AIDS Program at SFGH / ACTU
David Gary, RN
(415) 476-9296, ext. 354

New

8. HIV Infection: Leukocyte Interleukin

Title:

Leukocyte Interleukin Injection (LI): A Pilot Phase I Study in HIV-1 Infected Subjects

Type of treatment:

Leukocyte Interleukin: immune modulator

Purpose:

To see if leukocyte interleukin is safe when injected in persons with HIV infection and to see if it has any effect on CD4 cell counts, viral load and other immune cell functions.

About the study:

This is a dose escalating study. This means that the first patients to enter the study will receive the low dose of leukocyte interleukin. After two weeks, the next group of patients will enter the study at the higher dose. Leukocyte interleukin is given by injection under the skin five times a week (Monday - Friday). Those in the low dose group will be injected once a day; those in the high dose will be injected twice a day. Patients will be taught how to give themselves injections. Study visits will occur every two weeks and the study lasts eight weeks.

Required:

- CD4 cell (T-cell) range: 500 or greater
- Viral load range: between 500 and 50,000 copies
- HIV positive
- At least 18 years old
- Must be on stable triple antireroviral therapy (two reverse transcriptase inhibitors and one protease inhibitor) for at least three months prior to study entry

Not allowed:

- Any active opportunistic infections
- Women who are pregnant or breastfeeding
- Active substance abuse
- Any changes in antiretroviral therapy within the last 90 days
- Any significant cardiac, liver or nervous system diseases
- Use of any immune modulators such as interleukins, interferons, steroids, chemotherapy within 12 weeks of study entry
- Unintended weight loss of more than 10% in the past six months
- Any vaccinations or flu shots within 90 days of study entry
- Any cancers including Kaposi's Sarcoma

Location:

AIDS Research Alliance
Corie Castro
(310) 358-2429

New

9. HIV Infection: Cytolin

Title:

001: A 58 Day, Phase I/II. Open-Label, Pharmacokinetic and Dose-Ranging Study of Cytolin (a Whole Anti-Human Leukocyte Adhesion IgG1 Monoclonal Mouse Antibody) Using 16 HIV-Seropositive Adults

Type of treatment:

Cytolin: Monoclonal Mouse antibody

Purpose:

To compare the side effects and potential benefits of different doses of Cytolin

About the study:

This is a dose escalation study. This means that the first group of patients to enter the study will receive the lowest dose of Cytolin. If no bad side

effects are seen, the next group of patients will receive a higher dose of Cytolin, and so forth until the highest dose researchers plan to study has been given or the highest dose is found that causes no serious side effects. Cytolin is given once on day 1 by infusion into a vein. There are two screening visits. Study visits are every day for the first week, then on days 14, 21, 28, 30 56 and 58. The study lasts 58 days.

Required:

- CD4 cell (T-cell) range: between 200 and 500
- Viral load range: at least 50,000 copies
- HIV positive
- At least 18 years old
- Patients must be naive to antiretroviral medications OR have not taken any antiretroviral medications for the past two months OR have been on stable antiretroviral medication for the past two months and agree to continue it throughout the study

Not allowed:

- Any previous use of cytolin
- Women who are pregnant or breastfeeding
- Any chemotherapy within 8 weeks prior to study entry or the need for such during the study
- Any current acute illness
- Current substance abuse or other behavioral problems
- Current treatment with any immunomodulators

Location:

Beer Medical Group
Heather Robertson
(213) 937-5151

New

10. HIV Infection: DMP-266, Indinavir, AZT, 3TC

Title:

DMP-266-006: A 24 Week Phase II, Multicenter, Randomized, Open-Label Study to Compare Antiretroviral Activity and Tolerability of Three Different Combination Regimens (DMP-266 + Indinavir; DMP-266 + Zidovudine + Lamivudine; Indinavir + Zidovudine + Lamivudine) in HIV-Infected Patients

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
DMP-266: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To compare the safety and effectiveness of the three combinations. To see how long it takes to develop resistance to DMP-266

About the study:

Patients are assigned by chance to one of three treatments: DMP-266 + indinavir; DMP-266 + AZT + 3TC or indinavir + AZT + 3TC. Patients will know which treatment they are receiving. All medications are pills and taken by mouth. There are no placebos in this study. Study visits will be every four weeks and the study lasts for 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 10,000 copies
- HIV positive
- Between 13 and 60 years old
- Use of antiretrovirals must be discontinued at least two weeks prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of 3TC, DMP-266, any protease inhibitor or NNRTI (*eg.*, delavirdine, nevirapine)
- Use of any experimental drug within 30 days of study entry
- Currently being treated for any opportunistic infection or malignancy (cancer)
- Use of rifampin, rifabutin, fluconazole, ketoconazole, itraconazole, erythromycin, azithromycin, clarithromycin or greater than 1gram/day of Vitamin C throughout the study
- Active substance or alcohol abuse

Location:

AIDS Healthcare Foundation
Edwin Graham, RN
(213) 668-4843

Center for Special Immunology - Irvine
Sandra Casserella, RN
(714) 753-0670

Center for Special Immunology - San Diego
Norm Robert, LVN
(619) 291-1122

New

11. HIV Infection: Guanine Nuceloside Analog

Title:

A Randomized,Double-Blind, Placebo-Controlled, Multiple Ascending-Dose Pharmacokinetic and Safety Study of Intravenous Guanine Nuceloside Analog

Type of treatment:

Guanine Nucleoside Analog: antiretroviral, nuceloside analog

Purpose:

To see if guanine nuceloside analog is safe to take and to see how it is processed by the body.

About the study:

Patients will be required to stay in the hospital for 15 days. Patients will be assigned by chance to receive guanine nucleoside analog or placebo. Blood tests will be performed during the hospital stay. There will be a follow-up visit after the hospital stay. Patients will be paid up to $2,860 for completing this study.

Required:

- CD4 cell (T-cell) range: between 100 and 500
- Viral load range: not applicable
- HIV positive
- Between 18 and 65 years old

Not allowed:

- Current opportunistic infections

Location:

California Clinical Trials Medical Group
Clinic Staff
(800) 854-3902

New

12. HIV Infection: Indinavir, AZT, 3TC (4)

Title:

Merck 060: Multiclinic Open Study to Evaluate the Ability of the Combination of Indinavir, Zidovudine and Lamivudine to Result in Sustained Supression of HIV-1 in Asymptomatic HIV-1 Seropositive Patients

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To see if the combination of indinavir, AZT and 3TC can result in undetectable levels of HIV in blood and tissue and to see what happens to HIV levels when antiretroviral therapy is discontinued.

About the study:

All patients will receive indinavir, AZT and 3TC. Patients who achieve HIV viral load levels below the limit of detection for 48 consecutive weeks will have tests done to see if HIV is present in their lymph nodes, spinal fluid and semen. A lymph node biopsy and spinal tap will be required. If these results are negative and the viral load of the blood remains undetectable for an additional 72 weeks, patients will discontinue antiretrovirals and continue to be followed for long term outcome. Study visits are every month and the study lasts approximately four years.

Required:

- CD4 cell (T-cell) range: more than 500
- Viral load range: more than 1,000 copies
- HIV positive
- At least 18 years old
- Must not have had any treatment for HIV infection

Not allowed:

- Past or current use of antiretrovirals, protease inhibitors or immunomodulators
- Past or current AIDS-defining conditions

Location:

AIDS Community Research Consortium
Mari Steeno, RN
(415) 364-6563

New

13. HIV Infection: 141W94, Invirase, Nelfinavir, Indinavir

Title:

PROA2001: A Phase I/II Screening Trial to Identify Potential Partner Compounds to Use in Combination with 141W94

Type of treatment:

141W94: antiretyroviral, protease inhibitor
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
Invirase: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see if 141W94 is safe and to see if it is absorbed into the blood stream. To see if 141W94 has the ability to fight HIV when used in combination with other protease inhibitors.

About the study:

Patients are assigned by chance to receive 141W94 with either Soft Gel Invirase, Ritonavir or Indinavir or to receive 141W94 by itself. Those patients assigned to take 141W94 by itself will also take AZT and 3TC. All medications are pills and taken by mouth. Patients will know which medications they are taking. Study visits are once a week for the first month, then once a month. At week two, there will be an all day study visit to perform multiple blood draws. The study lasts 6 months with a possible extension.

Required:

- CD4 cell (T-cell) range: At least 200
- Viral load range: more than 20,000 copies
- HIV positive
- At least 18 years old

Not allowed:

- All antiretrovirals must be discontinued for two weeks prior to study entry
- Prior use of any protease inhibitors or immunomodulators
- Any radiation or chemotherapy within four weeks of study entry
- Concurrent use of clarithromycin, dapsone, rifampin, itraconazole, ketoconazole or rifabutin

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

New

14. HIV Infection: Indinavir, Nelfinavir

Title:

Merck 061: A Multicenter, 24-Week Study of the Safety, Pharmacokinetics, and Activity of the Coadministration of Indinavir and Nelfinavir in HIV-1 Seropositive Patients

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see if indinavir (Crixivan) and nelfinavir (VIRACEPT) are safe and effective in fighting HIV when taken together. To see how indinavir and nelfinavir are processed by the body.

About the study:

In Panel A, patients are assigned by chance to receive indinavir plus the lower dose of nelfinavir or to receive placebos for the first week. At week 2, patients assigned to take real drug will increase their dose of nelfinavir, while the group assigned to placebos will continue to take placebos during week 2. During week 3, patients assigned to take real drug will continue to take indinavir plus the higher dose of nelfinavir. Patients assigned to take placebos will switch to indinavir plus the lower dose of nelfinavir. During week 4, all patients will take indinavir and the higher dose of nelfinavir for the remainder of the study. After it has been determined that the dosages in Panel A are safe, patients will be enrolled in Panel B. Patients in Panel B are assigned by chance to receive indinavir plus nelfinavir or to receive placebos. After 15 days, all patients will receive indinavir plus nelfinavir (no placebos) for the remainder of the study. Study visits are once a week for the first month, then once a month thereafter. Study visits will include physicals and blood and urine tests. On day 29 all patients will have a catheter inserted into a vein for multiple blood draws all day. Patients will be in this study for 24 weeks.

Required:

- CD4 cell (T-cell) count: at least 100
- Viral load range: at least 30,000 copies
- HIV positive
- At least 18 years old

Not allowed:

- Prior use of any protease inhibitors
- Current opportunistic infections
- Current diagnosis of hepatitis
- Diagnosis of KS of the internal organs

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

New

15. HIV Replication and Nutrition: Ritonavir, Invirase, Advera

Title:

Effect of Combined Protease Inhibitors With or Without Nutritional Supplementation on T-Lymphocyte Kinetics, Apoptotic Pathways and Nutritional Status in HIV Disease

Type of treatment:

Advera: nutritional supplement
Invirase: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To see how protease inhibitors (along with the patients' nucleoside or non-nucleoside analogs) and nutritional supplements affect the rates of T-cell production and destruction.

About the study:

Patients entering this study will begin a four week phase during which they will stop taking any vitamins or mineral supplements. They will receive dietary counseling and be trained how to record a food intake diary. Some patients will also be assigned by chance to receive Advera, a nutritional supplement, during those four weeks. After four weeks, patients will be hospitalized for a 48 hour study including an infusion and blood draws. Patients will return to the clinic for the next seven days for blood tests. All patients will then start taking ritonavir and Invirase (saquinavir) in addition to their current antiretroviral

therapy. After 12 weeks, patients will be hospitalized again for another 48 hour test period. After the second hospital stay, patients may choose to continue receiving the protease inhibitors at no charge for six months, with T-cell counts and viral load tests every six weeks. Patients will be paid between $925 - $1,125 for completing this study.

Required:

- CD4 cell (T-cell) range: between 50 and 350
- Viral load range: at least 10,000 copies
- HIV positive
- At least 18 years old
- Stable (no changes) antiretroviral therapy for at least 30 days prior to study entry

Not allowed:

- Any acute opportunistic infection
- Women who are pregnant or breastfeeding
- Pancreatitis during the past two years or chronic pancreatitis
- Prior use of any protease inhibitor except Crixivan
- Use of any investigational drug within 30 days prior to study entry

Location:

UCSF General Clinical Research Center
Becky Hoh, RD
(415) 476-3669

16. HIV Infection: AZT, ddI

Title:

ACTG 276: A Multicenter Phase II Double-Blind Exploratory Study to Evaluate the Differences Among Various ZDV/ddI Regimens on Quantitative Measures of Viral Burden in Relatively Early HIV-1 Infection

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To learn about the effect of various combinations of AZT and ddI on lowering HIV viral load in patients with more than 550 CD4 cells (T-cells).

About the study:

Patients will be assigned by chance to take either AZT + ddI, AZT + placebo, or ddI + placebo, or placebo alone. Neither the patient nor their doctor will know which they are taking until the study ends. One-third of the patients assigned to take AZT + ddI placebo will be switched to ddI + AZT placebo after 16 weeks. One-third of the patients assigned to take AZT + ddI placebo will be switched to ddI + AZT after 16 weeks. Patients assigned to take ddI + AZT placebo will be switched to AZT + ddI placebo after 16 weeks. AZT and ddI are taken by mouth. There is a 2 week observation period at the beginning of the study. Patients will receive study drugs for 32 weeks, and there will be a 4-week observation period at the end of the study. Patients are reimbursed $20 per visit.

Required:

- CD4 cell (T-cell) range: at least 550
- HIV positive
- 13 years or older

Not allowed:

- Ever used antiretroviral drugs (AZT, ddI, ddC, d4T, 3TC, etc.)
- Taken systemic immunomodulators (gp120, gp160, IL-2 and interferons) in past 3 months
- Pregnant women
- Ever had peripheral neuropathy or pancreatitis

Location:

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

17. HIV Infection: HBY 097, AZT

Title:

HBY097/2001: A Randomized, Double-Blind, Dose-Escalation Study Evaluating the Safety and Antiretroviral Activity of HBY 097 vs HBY 097 plus AZT in Patients With Asymptomatic or Mildly Symptomatic HIV Infection.

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
HBY 097: antiretroviral, reverse transcriptase inhibitor

Purpose:

To see how safe and effective different doses of the new drug HBY 097 are when taken alone and in combination with AZT. To see how well HBY 097 is processed by the body.

About the study:

This is a dose-finding study. This means that the first group to enter the study will be given the lowest dose of HBY 097. If there are no bad side effects observed, the next group of patients will enter the study at a higher dose of HBY 097. Patients are assigned by chance to receive one of two treatments; HBY 097 plus AZT placebo or HBY 097 plus AZT. Neither patients nor their doctors will know which treatment is being taken until the study ends. Study visits will be every week for the first 4 weeks; then every other week up to 14 weeks. The study lasts a total of 3 months.

Required:

- CD4 cell (T-cell) range: 200 to 500
- At least 13 years old
- HIV positive
- Never taken antiretroviral drugs before (less than four weeks total of AZT, ddI, ddC, d4T, etc.)
- Few or no symptoms of HIV disease

Not allowed:

- Past or current AIDS-defining diagnosis
- Pregnant or nursing females
- Use of oral contraceptives

Location:

LAC-USC Medical Center
Frances Canchola, RN
(213) 343-8281

18. HIV Infection: Transfusion

Title:

SPIRAT2: A Pilot Study of HIV Specific CD8+ Cytoxic Lymphocyte (CTL) Therapy in HIV-Infected Patients with CD4 T-Cells of 200 or Less

Type of treatment:

Dendritic CellTransfusion

Purpose:

This is a study of a new cell therapy for HIV infection, using a type of white blood cell which fights infections in the body. These infection-fighting white blood cells are called dendritic cells. They will be donated by an HIV-negative sibling (brother or sister), and will be infused (injected) into a vein of the person with HIV. The purpose of the study is to see if infusions of dendritic cells are safe and if they help the immune system fight HIV.

About the study:

Patients will be given infusions of blood cells (similar to a transfusion) from a brother or sister. Several screening visits over a 3 month period are necessary to make sure blood cells from the patient and his or her sibling are compatible. After the screening period patients receive one infusion each month for 3 months. Patients will be required to stay 24 hours in the hospital for each infusion for observation of side effects. Patients will have study visits twice a month and the study lasts 12 months.

Required:

FOR PATIENT:

- CD4 cell (T-cell) range: 200 or less
- HIV positive
- Same cell type as sibling (to be determined by research staff)
- Must be taking some type of anti-HIV drug, (such as AZT, ddI, ddC, d4T or 3TC) at a stable dose during the screening and treatment periods of the study
- At least 18 years old

FOR DONOR:

- HIV negative
- Able to donate on three occasions
- Hepatitis B & C negative
- Weigh more than 110 lbs
- At least 18 years old

Not allowed:

- Active opportunistic infections
- Chronic diarrhea
- Wasting syndrome
- Any malignancy requiring systemic chemotherapy
- Any autoimmune disease or significant cardiovascular disease
- History of receiving any HIV vaccine or use of IL-2 in the last 6 months

Location:

Stanford University Medical Center
Pat Cain, RN
(415) 723-6231

19. HIV Infection: AZT, 3TC. Delavirdine

Title:

M/331/0021: A Double-Blind, Randomized, Combination Therapy Trial of Delavirdine (DLV) + Zidovudine (ZVD) plus Lamivudine (3TC) versus DLV plus ZVD versus ZVD plus 3TC as Initial Therapy or Following Part 1 Therapy in HIV-1 Infected Individuals with CD4 Counts of 200 - 500/mm^3.

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To find out if the drug delavirdine mesylate (also called DLV, U-90) combined with AZT and 3TC is better than AZT plus 3TC or AZT plus DLV in treating people with HIV. U-90 is a drug that is supposed to work against HIV in a different way than AZT or drugs like it. (It is called a non-nucleoside reverse transcriptase inhibitor, or RTI.)

About the study:

Patients are assigned by chance to one of three groups. One group will receive AZT plus delavirdine plus 3TC. Another group will receive AZT plus delavirdine plus 3TC placebo. The other group will receive AZT plus 3TC plus delavirdine placebo. All medications are pills and taken by mouth. Neither patients nor their doctors will know which they are receiving until the study ends but all patients will be receiving at least two 'real' medications (not placebos). Study visits are required every two weeks for the first two months, every month for the following four months, then every two months for the rest of the study. Patients continuing from Part 1 will be on this study for as many months as necessary to total two years. New patients to this study will be in this study for two years.

Required:

- CD4 cell (T-cell) range: 200 to 500
- Viral load range: not applicable
- At least 14 years old

Not allowed:

- Taking AZT for more than 6 months
- Having ever taken anti-HIV drugs that work in a similar way to AZT or U-90, such as ddI, ddC, d4T, 3TC, L-drugs, TIBO, HEPT, atevirdine, APA
- Current significant opportunistic infection, nervous system disorder, or muscle disease
- Women who are pregnant or breastfeeding

Location:

Davies Medical Center HIV Institute
Trisha Harasty
(415) 565-6222

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

Harbor-UCLA Medical Center
Crystal Lane, RN
(310) 222-3848

King - Drew Medical Center
Bessie Hughes
(310) 603-4213

Peachwood Medical Center
Eva Murphy
(209) 324-6257

Shared Medical Research Foundation
Vicky Ramirez
(818) 345-2172

UC Davis Medical Center
Michael Peterson
(916) 734-8282

UC Irvine Medical Center
Josephine Mosquara
(714) 456-7612

20. HIV Infection: GEM 91

Title:

91-007: A Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Safety, Pharmacokinetic and Preliminary Antiviral Activity Study of GEM 91 Administered by Continuous Intravenous Infusion in HIV-Positive Adults. (Phase Ib/II)

Type of treatment:

GEM 91: antiretroviral ("antisense")

Purpose:

To learn about the effects of the new drug GEM 91 in people with HIV. To compare the safety of several different doses of GEM 91. To collect short-term information about the antiviral effects of GEM 91.

About the study:

Patients are assigned by chance to receive GEM 91 or placebo. Neither patients nor their doctors know which they are receiving until the study ends. This is also a "dose escalation" or "dose finding" study, which means that the first few people to join will receive the lowest dose of the drug or placebo. If no bad side effects are seen after two weeks of treatment, the next group receives a slightly higher dose and so on until five different doses are tested. GEM 91 is given as an infusion into a vein. The study lasts a total of seven weeks. Because this is a new drug, the study requires very frequent clinic visits; a total of twenty visits, including every day for two weeks in a row, are required.

Required:

- CD4 cell (T-cell) range: 100 to 500
- Viral load range: more than 25,000 copies
- HIV positive, few or no symptoms
- At least 18 years old
- No active AIDS-related illness requiring treatment during the study
- Any drugs affecting the kidney (except Septra/Bactrim) during the study
- Researchers prefer people who do not require other medications during the study. Septra/Bactrim for PCP prevention is allowed, but most other drugs, including antiretrovirals and MAC and fungal infection prevention drugs are not allowed.

Not allowed:

- Pregnant or breastfeeding women
- Active alcohol or substance abuse
- Current infections or cancers requiring treatment

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

21. HIV Infection: AR-177

Title:

A Phase I Study to Determine the Safety and Pharmacokinetic Profile Following Single Doses of AR-177

Type of treatment:

AR-177: antiretroviral, integrase inhibitor

Purpose:

To see how safe different doses of the new drug AR-177 are and to see how AR-177 is processed by the body.

About the study:

This is a dose-escalating study. This means that the first group of patients entering the study will receive the lowest dose of AR-177. If no bad side effects are observed, the next group of patients will receive a higher dose of AR-177 and so forth until the maximum dose has been given. Patients will know which dose they are receiving. AR-177 is given by infusion into a vein once

over a two hour period. Study follow-up lasts 14 days. AR-177 is a new type of drug which acts against HIV in a different way than any other medication currently available. Participants are paid $250 for completing the study.

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: not applicable
- HIV positive
- At least 18 years old

Not allowed:

- Any previous or current AIDS-defining illness
- Substance abuse including tobacco (within the past 3 months)
- Pregnant or nursing females

Location:

UCSF AIDS Program at SFGH/ICTG
John Melichar
(415) 476-9296 ext. 309

22. HIV Infection: Methotrexate

Title:

DATRI 013: A Phase I Study of Methotrexate for HIV Infection.

Type of treatment:

Methotrexate: chemotherapy

Purpose:

To learn if the drug methotrexate has any anti-HIV effects.

About the study:

Patients will be assigned by chance to receive one of three doses of methotrexate. Patients will know which dose they are receiving. Methotrexate is taken by mouth. The study lasts 20 weeks and requires visits every other week.

Required:

- CD4 cell (T-cell) range: greater than 300
- HIV positive
- At least 18 years old
- Patients on antiretrovirals or protease inhibitiors must have been taking them for at leat the past 30 days

Not allowed:

- Any new AIDS-defining illnesses in the past 60 days

Location:

Cedars-Sinai Medical Center
Jacqui Pitt, RN
(310) 855-3755

23. HIV Infection: Indinavir, AZT, 3TC

Title:

ACTG 320: A Randomized, Double-Blind, Phase III Study of Indinavir Sulfate (IDV) with Open-Label Zidovudine (ZDV) or Stavudine (d4T) and Lamivudine (3TC) in Subjects with HIV Infection with CD4 Cell Counts of 200 or Less and 3 Months or More of Prior ZDV Experience

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To learn about the safety and effectiveness of IDV when given in combination with AZT (ZDV) or stavudine (d4T) and 3TC.

About the study:

Patients are assigned by chance to receive either IDV with AZT (or d4T) and 3TC or placebo with AZT (or d4T) and 3TC. Neither patients nor their doctors will know whether they are receiving IDV or placebo until the study ends. All drugs are taken by mouth. In some cases, patients will be able to switch from AZT to d4T after the first 24 weeks of study treatment. In some cases, patients will be able to switch from study treatment to open-label (real) IDV. Study visits and blood draws take place at screening, pre-entry, entry and weeks 4 and 8, then every 8 weeks until the study ends.The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: 200 or less
- At least 18 years old
- Three months or more of AZT therapy at any time before study entry

Not allowed:

- More than one week cumulative use of 3TC
- Use of rifampin or rifabutin within 14 days before starting the study
- Unable to tolerate at least 600 mg/day of AZT
- History of pancreatitis
- Acute hepatitis within 30 days before starting this study
- Diarrhea for 15 out of the 30 days before starting this study
- Women who are pregnant or breastfeeding

Location:

AIDS Community Research Consortium
Debbie Carroll, RN
(415) 364-6563

Children's Hospital of Los Angeles
Antonieta Sosa
(213) 668-2180

Harbor-UCLA Medical Center
Petra Miller
(310) 222-3848
-continued-

Kaiser San Francisco - HIV Research Unit
Susan Kirk, RN
(415) 202-3484

LAC-USC Medical Center
Connie Olson, RN
(213) 343-8279

Stanford University Medical Center
Jane Norris, PA
(415) 723-6231

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

24. HIV Infection: rgp160 Vaccine

Title:

ACTG 246: A Phase I/II, Double-Blind Controlled Trial to Determine the Safety and Immunogenicity of HIV-1 MN rgp160 Immuno/Ag Vaccine Therapy in HIV-Infected Individuals With Greater Than or Equal to 50 CD4 T-Cells

Type of treatment:

Vaccine, HIV: vaccine

Purpose:

To see if rgp160 is safe and to see if it is effective in producing antibodies in people with HIV. Effectiveness will be measured by CD4 (T-cell) counts and skin test reactions.

About the study:

Patients will be assigned by chance to receive rgp160 vaccine or placebo. Both are given as injections into a muscle. Injections are given every four weeks for the first six months, and then every eight weeks until one year after the last patient has been enrolled. Study visits will occur at the same time as injections. Patients will be on this study until one year after the last patient has enrolled.

Required:

- CD4 (T-cell) range: at least 50
- HIV positive
- At least 13 years old
- Less than 12 months prior use AZT

Not allowed:

- Ever taken any other antiretroviral (ddI, ddC, d4T, 3TC)
- Taken AZT for more than 12 months
- Any HIV vaccine
- Women who are pregnant or nursing
- Chronic diarrhea
- Allergy to any vaccine component

Location:

Stanford University Medical Center
Pat Cain, RN
(415) 723-6231

25. HIV Infection: rhIL-12 (I)

Title:

W-AR 879A2-205-US: A Randomized, Double-Blind, Placebo-Controlled, Dose-Escalating, Multiple-Dose Study of the Safety of Subcutaneous Recombinant Human Interleukin-12 (rhIL-12) in HIV-Infected Subjects

Type of treatment:

Interleukin-12: immune modulator

Purpose:

To learn about the safety of Interleukin-12 (rhIL-12, IL-12) at three different dose levels

About the study:

Patients are assigned by chance to receive the lowest of three doses of IL-12 or placebo. If no bad side effects are observed, the next patients to enter the study are assigned by chance to the middle dose of IL-12 or placebo. The last group of patients to enroll will receive either the high dose of IL-12 or placebo. IL-12 and its placebo are given by injection under the skin. Injections are given twice a week and the study lasts 16 weeks.

Required:

- CD4 (T-cell) range:100 to 500
- HIV RNA: 5000 equivalents or greater (to be tested by the researchers)
- HIV positive
- Must be on a stable combination of antiretrovirals for 6 weeks before the study
- Between 18 and 60 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Any AIDS-defining opportunistic infections (except PCP which has been treated)

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

26. HIV Infection: Tucaresol

Title:

Protocol 110-101: A Multicenter, Open-Label, Dose-Escalation, Pilot Study of Tucaresol (589C80) in HIV-Infected Patients with Moderate Immune Suppression (CD4+ Cell Counts of 300-500/mm^3), Incorporating Amendments 1 and 2

Type of treatment:

Tucaresol: immune modulator

Purpose:

To see how safe and effective the new drug tucaresol is for treating HIV infection. To compare the safety and effectiveness of different doses and different dosing schedules on the amount of HIV in the blood (viral load). To learn how the body processes and eliminates tucaresol.

About the study:

This is a dose-escalation or dose-ranging study. This means that the first patients to enroll will receive the lowest dose of tucaresol. If there are no bad side effects, the next patients will enter the study at a higher dose. This plan continues until the highest dose researchers plan to study has been given. Study visits are every week and the study lasts 16 weeks. Participants will be paid $365 for completing the study.

Required:

- CD4 cell (T-cell) range: 300 to 500
- HIV positive
- At least 18 years old
- Must be on antiretroviral therapy for at least 3 but not more than 12 months and maintain that same therapy throughout the study

Not allowed:

- Any history of an AIDS-defining illness including KS
- Prior use of HIV vaccines, IL-2, alpha interferon, G-CSF, GM-CSF, or any experimental anti-HIV therapy
- Concurrent hepatitis B or past hepatitis C
- History of significant respiratory disease, such as asthma, emphysema, etc.
- Abnormal EKG or significant coronary or cardiovascular disease
- Women who are pregnant or nursing
- Current use of illegal street drugs

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

27. HIV Infection: Hydroxyurea, ddI, d4T

Title:

A Phase I/II Open-Label Study to Evaluate the Safety and Preliminary Efficacy of Hydroxyurea Alone or in Combination with ddI or ddI plus d4T in HIV-Infected Persons.

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Hydroxyurea: cytotoxic chemotherapy

Purpose:

To see if hydroxyurea alone or in combination with ddI and/or d4T is safe and effective in fighting HIV.

About the study:

Patients are assigned by chance to receive one of three treatments: hydroxyurea alone, hydroxyurea plus ddI, or hydroxyurea plus ddI and d4T. All medications are pills taken by mouth. Patients and their providers will know which treatment they are receiving. Study visits are every four weeks and the study lasts 68 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old

Not allowed:

- Pancreatitis within the past two years
- Active opportunistic infections which require treatment during the course of the study
- Ever used d4T or ddI before
- Any experimental drugs within 21 days before starting the study
- Pregnant or breastfeeding women

Location:

Shared Medical Research Foundation
Vicky Ramirez
(818) 345-2172

28. HIV Infection: 3TC, Nevirapine

Title:

A Phase II/III, Double-Blind, Randomized Study of Current Antiretroviral Plus Lamivudine (3TC) Plus Viramune (nevirapine) in HIV-Infected Individuals with Less Than 200 CD4 Cells/mm^3

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor

Purpose:

To see if nevirapine is safe and effective when used with 3TC and added to current antiretroviral therapy.

About the study:

All patients entering this study will add 3TC to their current antiretroviral therapy. If patients are not currently taking antiretroviral medication, they will be given AZT with 3TC. If patients cannot tolerate AZT, they will only take 3TC. Patients are then assigned by chance to receive nevirapine or placebo. All medications are pills and taken by mouth. Neither patients nor their doctors will know whether they are taking nevirapine or not until the study ends. Study visits will be at week two and then every month. The study lasts two years.

Required:

- CD4 cell (T-cell) range: below 200
- HIV positive

Not allowed:

- Women who are pregnant or breastfeeding

Location:

Harbor-UCLA Medical Center
Crystal Lane, RN
(310) 222-3848

29. HIV Infection: Remune

Title:

IRC 806: A Multicenter, Double-Blind, Phase III, Adjuvant-Controlled Study of the Effect of 10 Units of Remune (HIV-1 Immunogen) Compared to IFA Alone Every 12 Weeks on AIDS-Free Survival in Subjects with HIV Infection and CD4 T Lymphocytes Between 300 and 549 Cells/mm^3 Regardless of Concomitant HIV Therapies

Type of treatment:

Remune: immune modulator

Purpose:

To see if Remune is safe and effective in slowing the progression of HIV infection to AIDS

About the study:

Patients will be assigned by chance to receive either Remune (also called HIV-1 Immunogen), or to receive a placebo (IFA). Both Remune and its placebo are given by injection into a muscle in the shoulder. Patients will receive injections every three months. Neither patients nor their doctors will know which they are receiving until the study ends. Study visits are every three months and the study lasts three years. Patients will have blood work done, such as CD4 cell counts and viral load at each three month visit. Patients may use any approved or investigational HIV therapy throughout the study.

Required:

- CD4 cell (T-cell) range: 300 to 549
- HIV positive
- At least 18 years old
- If taking any HIV therapy, must be on stable doses for the past three months
- Must not have taken any vaccine or immune modulators for three months prior to study entry and throughout the study

Not allowed:

- Pregnant or nursing women
- Any AIDS-defining illness including KS if it requires systemic chemotherapy
- Any alcohol or substance abuse problems which could interfere with the study
- Any acute infection requiring prescription therapy within one month of study entry (oral/vaginal thrush and genital herpes excepted)
- Current systemic chemotherapy for any cancers other than skin cancer
- Ever used Remune or HIV-1 Immunogen before

Location:

AIDS Community Research Consortium
Sharon O'Leary, RN
(415) 364-6563

AIDS Research Alliance
Corie Castro
(310) 358-2429

Cedars-Sinai Medical Center
Jacqui Pitt, RN
(310) 855-3755

Center for Special Immunology - Irvine
Sandra Casserella, RN
(714) 753-0670

Center for Special Immunology - San Diego
Norm Robert, LVN
(619) 291-1122

Jeffrey Goodman Special Care Clinic
Leigh Pearce
(213) 993-7548

Kraus Medical Partners
Cristina Dawes
(213) 930-2324

UCSF AIDS Program at SFGH/ICTG
Masa Fisher
(415) 476-9296 ext. 303

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

30. HIV Infection: VIRAMUNE (nevirapine), 3TC

Title:

1100.1090: An International, Double-Blind, Randomized, Phase-III Study to Evaluate the Tolerance, Safety and Effectiveness of VIRAMUNE (nevirapine) in Preventing Clinical AIDS Progression Events or Death When Used in Combination with Lamivudine (3TC) and Stable (Four Weeks or More) Backround Nucleoside Therapy

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor

Purpose:

To learn about the safety and effectiveness of VIRAMUNE, 3TC and backround therapy compared to 3TC and backround therapy alone. Backround therapy is AZT, AZT + ddC or AZT + ddI. If patients cannot tolerate AZT, then ddI, ddC or d4T monotherapy is allowed.

About the study:

Patients will be assigned by chance to receive VIRAMUNE or its placebo. Neither patients nor their doctors will know which they are receiving until the study ends. All patients will take 3TC in addition to the same antiretroviral therapy they were taking when joining the study. VIRAMUNE and 3TC will be paid for by the study but the patient is responsible for obtaining his/her antiretroviral medications. There are two screening study visits, a baseline study visit, a two-week study visit, then every month for the first eight months.

After eight months, study visits will be every two months. The study lasts 18-24 months.

Required:

- CD4 cell (T-cell) range: 200 or less
- HIV positive
- At least 13 years old
- No change in antiretroviral therapy for four weeks prior to study: AZT, AZT + ddI or AZT + ddC. If AZT intolerant, ddC, ddI or d4T monotherapy is allowed. Prior use of 3TC is allowed if less than three months

Not allowed:

- Prior treatment with nevirapine or any other non-nucleoside reverse transcriptase inhibitor (delavirdine, loviride)
- Use of any protease inhibitors within four weeks before the study
- Use of any antiretrovirals other than AZT, ddC, ddI, d4T or 3TC
- Taking any acute therapy for clinical AIDS progression (chemotherapy or radiation for KS)
- Use of any immunosuppressive or cytotoxic drugs within two weeks of study entry
- Any alcohol, drug abuse or psychiatric problems which might interfere with the study
- Women who are pregnant or breastfeeding
- Use of erythromycin, coumadin/warfarin, phenobarbital, amoxicillin/clavulanic acid or ticarcillin/clavulanic acid, dicumarol, tolbutamide, vincristine and cimetidine within two weeks of study entry

Location:

Tower Infectious Diseases
Jennifer Ida, PharmD
(310) 358-2300 ext. 228

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 313

31. HIV Infection: Oral Alpha Interferon

Title:

DATRI 022: A Multicenter, Prospective, Randomized, Double-Blind, Placebo-Controlled Trial of Three Preparations of Low-Dose Oral Alpha Interferon in HIV-Infected Patients with CD4 Counts Between 50 and 350 Cells/mm^3

Type of treatment:

Oral Alpha Interferon: Immunomodulator

Purpose:

To see what effects three different doses of oral alpha interferon have on HIV symptoms and body weight.

About the study:

Patients will be assigned by chance to one of three different doses of oral alpha interferon or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. This form of alpha interferon is a pill and taken by mouth. Study visits will occur every four weeks and the study lasts six months.

Required:

- CD4 cell (T-cell) range: Between 50 and 350
- HIV positive
- At least 13 years old
- Patients who are on antiretroviral therapy must not have made any changes to that therapy for at least six weeks

Not allowed:

- Any change in antiretroviral therapy within the last six weeks
- Any use of alpha interferon or any other immunomodulator within one month of study entry
- Therapy for any acute disease within one week of study entry
- Women who are pregnant or breastfeeding

Location:

AIDS Community Research Consortium
Sharon O'Leary, RN
(415) 364-6563

King-Drew Medical Center
Laurie Tolbert
(310) 668-4213

32. HIV Infection: bis-POM-PMEA

Title:

GS-96-408: A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Adefovir Dipivoxil (bis-POM-PMEA) When Added to Standard Antiretroviral Therapy for the Treatment of HIV-Infected Patients With CD4 Cell Counts of 200/mm^3 or More.

Type of treatment:

bis-POM PMEA: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if adefovir dipivoxil (bis-POM-PMEA) is a safe and effective treatment for HIV infection.

About the study:

Patients are assigned by chance to receive bis-POM-PMEA or placebo to take in addition to their current antiretroviral medications. Neither patients nor their doctors will know which they are taking until the study ends. Both bis-POM-PMEA and its placebo are pills and taken by mouth. After 24 weeks, all patients will take open-label (real) bis-POM-PMEA for an additional 24 weeks. Study visits are once a month and the study lasts 48 weeks. Study visits will include blood tests and physical exams.

Required:

- CD4 cell (T-cell) range: At least 200
- HIV positive
- At least 13 years old
- HIV RNA titer of at least 2,500eq/mL
- Must be taking the same approved antiretroviral therapy(ies) for at least eight weeks before starting the study and maintain these same medications throughout the first 24 weeks of the study

Not allowed:

- Any new AIDS-defining infection within two months prior to study entry
- Use of any immunomodulators such as corticosteroids, interleukins or interferons within four weeks prior to study entry
- Women who are pregnant or breastfeeding
- Current alcohol or substance abuse which may interfere with study schedules
- Any cancers other than KS of the skin or basal cell carcinoma. Any patients with KS of the skin must not have received any systemic chemotherapy within four weeks prior to starting the study

Location:

AIDS Community Research Consortium
Sharon O'Leary, RN
(415) 364-6563

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

Harbor-UCLA Medical Center
Dena Duran
(310) 222-3848

Kraus Medical Partners
Lynn Sarfaty
(213) 930-2324

Pacific Oaks Research Group
Anne Blackburn, RN
(310) 275-9346

Santa Clara Valley Medical Center
Carol Kane, RN-A
(408) 885-4316

UCSF AIDS Program at SFGH/ICTG
Masa Fisher
(415) 476-9296 ext. 303

33. HIV Infection: Hydroxyurea, ddI

Title:

ACTG 307: A Phase I/II Dosing Study of the Safety and Antiretroviral Activity of Hydroxyurea Alone and in Combination with ddI Compared to ddI Alone in Subjects with HIV Infection

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Hydroxyurea: cytotoxic chemotherapy

Purpose:

To see if hydroxyurea alone, or ddI alone, or a combination of the two is a safe and effective treatment for HIV infection. To see which dose of hydroxyurea is safest and best tolerated when taken with ddI.

About the study:

Patients are assigned by chance to one of five different groups. Patients will receive either hydroxyurea alone, ddI alone, or a combination of both using two different doses of hydroxyurea. Neither patients nor their doctors will know which treatments they are taking until the study is over. Patients assigned to receive hydroxyurea alone will have the ddI placebo changed to active ddI after four weeks. After 12 weeks, patients are assigned by chance again to receive either one of two doses of open-label (real) hydroxyurea plus open-label (real) ddI for an additional 12 weeks. About three visits are required before starting the study; then study visits will occur every two weeks until week eight. After week eight, study visits will occur once a month until the end of the study. The study lasts 24 weeks but a week 28 post-study visit is required. On the day of study drug dosing and on the week two visit, patients should plan on spending some time at the clinic as six blood draws are required on those days.

Required:

- CD4 cell (T-cell) range: Between 200 and 700
- HIV positive
- Must stop all current antiretroviral therapy for 14 days before starting the study and remain off all therapy for the duration of the study
- At least 18 years old

Not allowed:

- Severe peripheral neuropathy
- Any use of ddI for more than two weeks
- Previous use of hydroxyurea
- Women who are pregnant or breastfeeding
- Active substance abuse which could interfere with the study
- Any cancers which will require chemotherapy within the next 24 weeks
- Past pancreatitis or current alcohol abuse
- Treatment with any vaccine or immunomodulators within the past 30 days
- Treatment with any blood transfusions, G-CSF, GM-CSF or EPO within the last 60 days

Location:

Harbor-UCLA Medical Center
Mario Guerrero
(310) 222-3848

-continued-

Kaiser San Francisco - HIV Research Unit
Susan Kirk, RN
(415) 202-3484

Stanford University Medical Center
Pat Cain, RN
(415) 723-6231

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

34. HIV Infection: d4T, 3TC, AZT, Indinavir

Title:

A Randomized, Double-Blind Study of the Safety, Virologic and Immunological Effects of d4T + 3TC versus AZT + 3TC in HIV Positive Patients Following at Least 6 Months of AZT Therapy

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see which combination, d4T and 3TC or AZT and 3TC, is safer and more effective in fighting HIV infection.

About the study:

Patients are assigned by chance to receive AZT + 3TC + d4T placebo or d4T + 3TC + AZT placebo. Neither patients nor their doctors will know which they are receiving until the study ends. If patients still have a detectable viral load after 12 weeks, indinavir (Crixivan) will be added. Study entry will requires two or three visits. Study follow-up visits are every four weeks and the study lasts six months.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- HIV RNA viral load of at least 10,000 copies
- Must have used AZT, either alone or in combination, for at least six months anytime in the past, and be on AZT at study entry

Not allowed:

- May not have ever taken any antiretroviral drugs other than AZT, ddI or ddC

Location:

Harbor-UCLA Medical Center
Crystal Lane, RN
(310) 222-3848

35. HIV Infection: Viral Load Analysis (I)

Title:

A Randomized Clinical Study to Determine the Efficacy of HIV RNA Viral Load as a Marker for Determining Treatment Regimens for HIV-Infected Patients Who Enter the Study with a CD4 Count of 300 to 750 Cells/mm^3

Type of treatment:

Observational: none

Purpose:

To determine whether and to what extent using HIV viral load tests is a better target for therapy changes than CD4 (T-cell) counts.

About the study:

Patients are assigned by chance to a predetermined decision-making plan for modifying medication based on viral load or based on CD4 counts. Patients assigned to the viral load group will have the results used to determine treatment changes. When the treatment plan calls for a protease inhibitor, indinavir (Crixivan) will be paid for by the study. Those assigned to CD4 counts alone will not know their viral load results until the study is over. Study visits are every three months with telephone contacts every six weeks. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: Between 300 and 750
- HIV positive
- At least 18 years old

Not allowed:

- Use of any protease inhibitor or any three-combination antiretroviral combination prior to starting the study
- Any prior opportunistic infection or AIDS-defining event
- Any cancer requiring systemic chemotherapy
- Severe peripheral neuropathy
- Current or past pancreatitis
- Proven or suspected hepatitis in the past 30 days
- Patients with over 500 T-cells may not have used any antiretroviral treatment within 30 days

Location:

Kaiser San Francisco - HIV Research Unit
Sylvia Borgonovo, RN
(415) 202-3480

Kaiser San Francisco - HIV Research Unit
Marianne McFarland, RN
(415) 202-3480

36. HIV Infection: Viral Load Analysis (2)

Title:

CCTG 570: A Randomized, Prospective, Phase II Study of the Utility of Using HIV RNA Plasma Levels to Modify Antiretroviral Therapy in Patients with CD4 Counts of Less Than 300 Cells

Type of treatment:

Observational: none

Purpose:

To see if using HIV RNA viral load (bDNA lab tests) in addition to current clinical care (CD4 T-cell counts and/or disease progression) in deciding when to change therapy is more effective than deciding to start or change therapy based on current clinical care alone.

About the study:

Patients are assigned by chance to a decision-making plan for modifying medication based on viral load and current clinical care or on current clinical care alone. All patients will have HIV RNA viral load tests done but only those assigned to the viral load group will have them used to determine treatment changes. The group assigned to current clinical care alone will not know their viral load test results until the end of the study. Study visits are every two months and the study lasts one year.

Required:

- CD4 cell (T-cell) range: below 300
- HIV positive
- At least 18 years old
- HIV RNA viral load: At least 5,000 copies/mL
- Able to tolerate at least two antiretroviral medications including medications the patient has not taken before

Not allowed:

- Women who are pregnant or breastfeeding
- Patients with any symptoms suggestive of an undiagnosed opportunistic infection or cancer
- Cancer requiring systemic chemotherapy or expected chemotherapy for the next 12 months
- Active alcohol or substance abuse that might interfere with study follow-up
- Chronic therapy for opportunistic infections that would limit antiretroviral therapy (for example, IV ganciclovir)
- Any treatment with immunomodulators, vaccines, gene therapy, antisense compounds in the last 90 days

Location:

Santa Clara Valley Medical Center
Carol Kane, RN-A
(408) 885-4316

37. HIV Infection: Alpha Interferon

Title:

IFN9501: A Phase II, Randomized, Placebo-Controlled, Double-Blind Evaluation of the Efficacy and Safety of Alferon N Injection (Alpha Interferon) as Compared to a Placebo Control in the Treatment of HIV+ Subjects

Type of treatment:

Interferon, alpha: immune modulator

Purpose:

To see if alpha interferon is safe and effective in fighting HIV as measured by HIV RNA viral load.

About the study:

Patients are assigned by chance to receive alpha interferon or placebo. Both alpha interferon and its placebo are given by injection under the skin. Injections are given three times a week. Neither patients nor their doctors will know which they are receiving until the study ends. The first five study visits will be every two weeks, then once every month. The study lasts seven months.

Required:

- CD4 cell (T-cell) range: At least 250
- HIV RNA viral load: At least 2,000 copies/mL
- HIV positive
- At least 18 years old
- Either no antiretroviral medication or stable (no changes) antiretroviral medication for at least 2 months prior to screening. FDA-approved protease inhibitors are allowed.

Not allowed:

- Current serious illnesses or opportunistic infections or cancers which could interfere with study guidelines
- Past or current neuropsychiatric disorders such as major psychoses, major depression or anxiety disorders
- Active injection drug users
- Any alpha interferon products within six months of study screening
- Past or current hyperthyroidism
- Use of corticosteroids within 30 days of study screening
- Any vaccinations within 30 days of study screening
- Women who are pregnant or breastfeeding

Location:

California Infectious Disease Associates
Carol Kane, RN-B
(800) 910-2432

Santa Clara Valley Medical Center
Carol Kane, RN-A
(408) 885-4316

Shared Medical Research Foundation
Vicky Ramirez
(818) 345-2172

38. HIV Infection: Indinavir, d4T, ddI, AZT, 3TC

Title:

BMS-002: An Open-Label, Randomized, Comparative Study of Zerit (d4T) + Videx (ddI) + Crixivan versus Retrovir (AZT) + Epivir (3TC) + Crixivan in HIV Seropositive Patients with CD4 Cell Counts of 200 - 700 mm^3, and HIV RNA Baseline Copy Number of at Least 10,000 Copies/mL

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To compare the combination of Crixivan (indinavir) combined with d4T + ddI versus Crixivan (indinavir) combined with AZT + 3TC to see which is more effective in fighting HIV infection.

About the study:

Patients are assigned by chance to receive d4T + ddI + Crixivan or to receive AZT + 3TC + Crixivan. All medications are pills and taken by mouth. Patients with four weeks or less treatment with AZT and/or ddI must stop taking AZT and/or ddI for two weeks prior to study entry. Study visits are once a month for six months, then every six weeks The study lasts one year.

Required:

- CD4 cell (T-cell) range: between 200 and 700
- HIV positive
- HIV RNA range: at least 10,000 copies/mL
- At least 16 years old
- Must not have taken any antiretrovirals before. Four weeks or less of AZT and/or ddI treatment is okay

Not allowed:

- Women who are pregnant or breastfeeding
- Any acute AIDS-defining condition requiring treatment within one month of study entry
- Past AZT or ddI-related toxicity
- Any cancers requiring current systemic chemotherapy
- Moderate-severe peripheral neuropathy
- Current or past pancreatitis
- Past history of kidney stones
- Hepatitis within 30 days of study entry
- Treatment with rifampin, rifabutin or ketoconazole within 14 days of study entry or during the study

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

39. HIV Infection: Invirase (Saquinavir), Indinavir (Crixivan)

Title:

ACTG 333: The Anti-Viral Effect of Switching from Hard Capsule Saquinavir (SQVhc) to the Soft Gelatin Capsule of Saquinavir (SQVsgc) versus Switching to Indinavir (IDV) After More Than One Year of Saquinavir Use

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
Invirase: antiretroviral, protease inhibitor

Purpose:

To see if patients who have been taking saquinavir (hard capsule) for greater than one year have a decrease in the amount of HIV in their blood after switching to saquinavir (soft gelatin) or switching to indinavir.

About the study:

Patients entering this study must have been taking saquinavir hard capsule for more than one year. Patients will be assigned by chance to continue taking saquinavir hard capsule or switch to saquinavir soft gel or switch to indinavir. Patients will continue to take their same non-protease inhibitor anti-HIV drugs, if any. After eight weeks, patients taking hard capsule will be switched to indinavir. Patients on soft gel and indinavir will continue on those drugs for 24 weeks unless they have no response to their new therapy. Response will be measured by viral load tests. Patients taking SQV soft gel who do not show a response will be switched to indinavir. Patients not responding on indinavir will be switched to SQV soft gel. Patients will have three viral load tests prior to starting the study. Study visits (and viral load tests) are done every two weeks for the first eight weeks. Study visits will then be scheduled differently depending on which medication patients are taking. The study lasts 52 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- Must have taken saquinavir hard capsule at 1800 mg/day for greater than one year
- At least 18 years old

Not allowed:

- Past use of any other protease inhibitor other than saquinavir hard capsule
- Any medication or dose changes of antiviral drug therapy within eight weeks of study entry
- Use of rifampin, rifabutin, cisapride, Seldane, Hismanal, Halcion, oral ketoconazole or delavirdine within 14 days of study entry. These medications are also prohibited throughout the study
- Acute therapy for infections within 14 days of study entry
- New onset (within 30 days of study entry) of unexplained fever for any 7 days
- Any cancer which requires or will require systemic chemotherapy within 8 weeks of study entry
- Women who are pregnant or breastfeeding

Location:

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

Kaiser San Francisco - HIV Research Unit
Susan Kirk, RN
(415) 202-3484

Stanford University Medical Center
Pat Cain, RN
(415) 723-6231

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

40. HIV Infection: DMP-266; AZT, 3TC (I)

Title:

266-005: A Phase II, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Assess the Antiretroviral Activity and Safety of DMP-266 in Combination with Open-Label Zidovudine (ZDV) and Lamivudine (3TC) in HIV-Infected Patients

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
DMP-266: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see which dose of DMP-266 is safest and most effective in treating HIV infection.

About the study:

Patients are assigned by chance to receive one of three doses of DMP-266 or placebo to take with AZT and 3TC. Neither patients nor their doctors will know whether they are taking DMP-266 or placebo, or what dose they are taking until the study ends. All patients will take actual (no placebos) AZT and 3TC. Study visits will occur every two to four weeks for the first two months, then every month. The study lasts at least 24 weeks but possibly longer. Some research sites may pay participants for their participation.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 10,000 copies/ml
- At last 18 years old

Not allowed:

- Previous treatment with any antiretrovirals or protease inhibitors
- Any past or current AIDS-defining opportunistic infections.

Location:

California Infectious Disease Associates
Carol Kane, RN-B
(800) 910-2432

Kraus Medical Partners
Julie Schaffer
(213) 930-2324

UCSF AIDS Program at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296, ext. 312

41. HIV Infection: CD4-zeta Gene Therapy

Title:

A-9501: A Phase II Study of the Activity and Safety of Autologous CD4-Zeta Gene Modified T Cells in HIV-Infected Patients

Type of treatment:

CD4-Zeta T Cells: gene therapy

Purpose:

To see if removing CD8 white blood cells from the body and treating them with a new gene called CD4-zeta, improves the CD8 cells' ability to attack the HIV virus. This process is sometimes referred to as "gene therapy".

About the study:

Patients are assigned by chance to receive three infusions of autologous CD4-zeta-modified T cells given three days in a row plus antiretroviral therapy OR antiretroviral therapy alone. Patients will give blood samples from which T cells are removed. Two human genes, CD4 and zeta, which occur

naturally in T cells, are combined to produce the CD4-zeta gene. The CD4-zeta gene is added to the patients' T cells. The modified T cells are then given to the patients as an infusion into a vein. Patients who are assigned to receive antiretroviral therapy alone may be offered modified T cells through a compassionate use protocol beginning one year after enrollment, depending on whether viral loads have decreased in patients who received the modified T cells.

Required:

- CD4 cell (T-cell) range: between 50 and 500
- Viral load range: at least 1,000
- HIV positive
- At least 13 years old
- Patients must be on stable (no changes) antiretroviral therapy

Not allowed:

- Any use of interleukin therapy in the past six months
- Any active opportunistic infections requiring treatment

Location:

UCSF AIDS Program at SFGH/ICTG
Anna Smith, RN
(415) 476-9296, ext. 313

42. HIV Infection: rIL-2

Title:

CS-I2002: A Phase II Randomized Multicenter Open Label Study of Subcutaneous Proleukin (Adesleukin) Chiron Recombinant Interleukin-2 with Standard of Care Antiretroviral Therapy versus Standard of Care Antiretroviral Therapy Alone in HIV Seropositive Patients With CD4 Cell Counts of 200-500 Cells/mm^3

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To compare IL-2 therapy plus standard antiretroviral therapy verus standard antiretroviral therapy alone. To see which treatment is safer and more effective in treating HIV disease.

About the study:

Patients are assigned by chance to receive IL-2 plus antiretroviral therapy or to receive antiretroviral therapy alone. IL-2 is given by an injection under the skin. Patients will know whether they are receiving IL-2 or not. Those patients assigned to receive IL-2 will be taught to give themselves injections at home. Injections will be given every 12 hours for five days in a row, then seven weeks of no injections. This is known as a cycle. There will be six cycles. The study lasts 18 months.

Required:

- CD4 cell (T-cell) range: between 200 and 500
- Viral load range: not specified
- HIV positive
- At least 18 years old
- Must have been on antiretroviral therapy either with approved or expanded access treatments for at least two weeks prior to IL-2 therapy

Not allowed:

- Any past use of IL-2
- Any cancers other than KS of the skin
- Any past AIDS-defining condition
- Use of steroids, chemotherapy, G-CSF or GM-CSF within four weeks of study entry
- Active substance abuse which could interfere with the study
- Antiseizure medications
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

43. HIV Infection: DMP-266, AZT, 3TC (2)

Title:

266-004: A Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability and Antiretroviral Activity of DMP-266 in Combination with Open-Label Zidovudine (ZDV) and Lamivudine (3TC) in HIV-Infected Patients

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
DMP-266: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if DMP-266 is safe and effective for treating HIV when taken in combination with AZT and 3TC. To see how DMP-266 is processed by the body. To see what the time frame is, if any, for resistance to DMP-266.

About the study:

Patients will be assigned by chance to receive one of two doses of DMP-266 or placebo to take with AZT and 3TC. Neither patients nor their doctors will know whether they are taking DMP-266 or placebo, or what dose they are taking until the study ends. All patients will take actual (no placebos) AZT and 3TC. All medications are pills and taken by mouth. Study visits will be every week for four weeks, then every two weeks for four weeks, then every four weeks up to 52 weeks. Patients will be paid for each study visit they complete.

Required:

- CD4 cell (T-cell) range: 100 to 500
- Viral load range: 5,000 or greater
- Between 13 and 60 years old
- HIV positive
- At least 8 weeks of stable therapy with AZT and 3TC

Not allowed:

- Any past or current AIDS-defining opportunistic infections
- Previous treatment with any non-nucleosides (such as delavirdine, nevirapine) or protease inhibitors
- Recurrent diarrhea and/or vomiting

Location:

Center for Special Immunology - Irvine
Sandra Casserella, RN
(714) 753-0670

Kraus Medical Partners
Lynn Sarfaty
(213) 930-2324

UCSF AIDS Program at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296, ext. 312

44. HIV Infection: 1592U89

Title:

CNAA2003: An Exploratory Study of the Antiretroviral Activity of 1592U89 when Administered in Combination with Other Specific Nucleoside Reverse Transcriptase Inhibitors (NRTI's) in NRTI-Experienced Patients

Type of treatment:

1592U89: antiretroviral

Purpose:

To see if 1592U89 is safe, effective, and well-tolerated for activity against HIV when combined with other specific antiretroviral therapy.

About the study:

All patients will receive 1592U89 to take in addition to their current antiviral treatment. There is no placebo in this study. 1592U89 is a pill and taken by mouth twice a day. There are 2 screening visits and eight study visits. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: At least 100
- Viral load range: At least 30,000
- At least 13 years old
- There are specific requirements for past antiretroviral treatment - please call for details

Not allowed:

- Pancreatitis or hepatitis in the past six months
- Any active or ongoing AIDS-defining opportunistic infection or disease

Location:

Kraus Medical Partners
Stanka Derzic
(213) 930-2324

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

45. HIV Infection: rhIL-12 (2)

Title:

ACTG 325: A Phase I Double-Blinded Trial of Recombinant Human Interleukin-12 (rhIL-12) in HIV-Infected Subjects With Less Than 50 CD4+ T Cells and Subjects With 300-500 CD4+ T Cells, Who Have No Evidence of Serious Ongoing Opportunistic Infections

Type of treatment:

Interleukin-12: immune modulator

Purpose:

To see how well interleukin-12 is tolerated and to see if it is safe and effective in treating HIV infection. To find out which of three different doses of rhIL-12 is safest to take.

About the study:

This is a dose-ranging study. Patients with less than 50 T-cells are assigned by chance to receive the lowest of three doses of interleukin-12 or placebo (Part A). If no bad side effects are seen, the next patients to enter the study are assigned by chance to receive the middle dose of interleukin-12 or placebo. If no bad side effects are seen at that dose, the third group of patients to enroll will receive the high dose of interleukin-12 or placebo. After this part of the study is completed, patients with 300 to 500 T-cells are assigned by chance to receive the highest dose of interleukin-12 which had no bad side effects or placebo (Part B). Interleukin-12 is given by injection under the skin. Injections are given twice a week. The study lasts four weeks.

Required:

- CD4 cell (T-cell) range: Part A: less than 50 Part B: between 300 and 500
- Viral load range: not applicable
- Between 18 and 60 years old
- HIV positive
- Patients must have been on stable antiretroviral therapy for at least four weeks before study entry
- Must be willing to take drugs to prevent *Pneumocystis carinii* pneumonia (PCP) (Part A only)

Not allowed:

- Current antiretroviral therapy with ddC or d4T
- Past history of MAC, CMV or any invasive fungal disease (such as cryptococcosis, histoplasmosis, coccidiomycosis, etc.)
- Any use of interleukin-12 within the past 24 weeks
- Women who are pregnant or breastfeeding

Location:

Stanford University Medical Center
Pat Cain, RN
(415) 723-6231

UCSF AIDS Program at SFGH/ACTU
Carol Arri, RN
(415) 476-9296 ext. 351

46. HIV Infection: PMPA

Title:

GS-96-701: A Phase I/II Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerance, Pharmacokinetics, and Antiviral Activity of 9-[(R)-2-(Phosphonomethoxy)Propyl]Adenine (PMPA) in HIV-Infected Patients

Type of treatment:

PMPA: antiretroviral, nucleoside analog

Purpose:

To see if PMPA is safe, well-tolerated and effective in treating HIV infection. To see how PMPA is processed by the body.

About the study:

This is a dose-escalating or dose-ranging study. This means that the first 10 patients to enroll will receive the lowest dose of PMPA. If there are no bad side effects, the next 10 patients to enroll will receive a higher dose and this plan is followed until all four doses of PMPA that researchers plan to study have been assigned. In each group of ten patients, there is a 20% chance of receiving a placebo. Neither patients nor their doctors will know which they are receiving until the study ends. PMPA is given by infusion into a vein and takes about one hour to complete. Patients will receive one infusion on day 1 followed by a one week observation period (part A). Each patient that completes part A with no bad side effects will begin part B. In part B, patients will receive PMPA or placebo by daily IV infusion for seven days at the same dose level as they received in part A. The study lasts about two months. At the end of the study, patients will have the option to receive real (no placebo) PMPA and patients will also have priority access to the oral formulation when it is available. Patients will be paid $500 for completing the study.

Required:

- CD4 cell (T-cell) range: At least 200
- Viral load range: At least 10,000 copies/ml
- HIV positive
- Between 18 and 60 years old

Not allowed:

- Active, serious infections requiring IV antibiotic treatment
- Women who are pregnant or breastfeeding
- Patients taking any antiretroviral treatment(s) must discontinue these treatments two weeks prior to study entry and through the remainder of the study.
- Past or current cancers other than basal cell of the skin or KS of the skin

Location:

UCSF AIDS Program at SFGH/ICTG
John Melichar
(415) 476-9296 ext. 309

47. Anogenital Warts Treatment: HPMPC (Cidofovir) Gel

Title:

GS-93-302: A Phase I/II Study of the Safety and Efficacy of Cidofovir Topical Gel (HPMPC) in the Treatment of Condyloma Acuminatum in Patients with HIV Infection

Type of treatment:

Cidofovir Topical Gel: antiviral

Purpose:

To see if cidofovir topical gel (also known as HPMPC) is safe and effective in treating Condyloma Acuminatum (warts on the anus or genitals) of patients infected with HIV.

About the study:

All patients in this study will apply cidofovir topical gel directly to their wart(s) once daily, five days a week for one to two weeks. A skin biopsy is required for this study. This means a small piece of tissue will be removed from a wart for the purpose of diagnosing Condyloma Acuminatum. The study lasts from four to eight weeks.

Required:

- CD4 cell (T-cell) range: at least 100
- HIV positive
- At least 18 years old
- Female patients only
- External anal or genital wart(s) that have failed at least one previous treatment

Not allowed:

- Any wart treatment within four weeks of study entry
- Active lesions of genital herpes, or any inflammatory skin condition in the same area as the wart
- Women with current evidence of a Grade III pap smear
- Women who are pregnant or breastfeeding

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

SFGH Dermatology
Mahpara Burney, MD
(415) 206-8680

48. Cervical Dysplasia Prevention: Isotretinoin

Title:

ACTG 293: A Randomized, Phase III Trial of Oral Isotretinoin versus Observation for Low Grade Cervical Dysplasia in HIV-Infected Women

Type of treatment:

Isotretinoin: skin cell growth stimulant

Purpose:

To see if oral isotretinoin is effective in preventing progression of mild dysplasia to more severe dysplasia by comparing the time to progression of Cervical Intraepithelial Neoplasia (CIN) I to CIN II, III or invasive cancer in patients receiving isotretinoin versus observation.

About the study:

Patients are assigned by chance to receive oral isotretinoin or to be observed. Isotretinoin is a pill and taken by mouth once a day for six months. Study visits are once a month for six months; then one visit at months 12 and 18.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Females only
- At least 13 years old
- Diagnosis of CIN I by cervical biopsy (done by research staff at the test site)

Not allowed:

- CIN II, III, or invasive cervical cancer
- Any cancer requiring systemic chemotherapy within three months prior to study entry
- Previous use of isotretinoin within three months prior to study entry
- Past topical treatment for genital warts within one month prior to study entry
- Past treatment for CIN II or III
- Pregnancy or breastfeeding

Location:

AIDS Community Research Consortium
Sharon O'Leary, RN
(415) 364-6563

LAC-USC Medical Center
Analyn Howells, RN
(213) 343-8277

LAC-USC Medical Center - Maternal Child Program
Nancy Creighton, RN
(213) 226-5068

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

New

49. Cervical Dysplasia Treatment: DFMO

Title:

DFMO-96-001: A Phase II Study of the Efficacy and Safety of Orally Administered DFMO in HIV-Infected Women With Cervical Intraepithelial Neoplasia (CIN II, III)

Type of treatment:

DFMO: anti-cancer

Purpose:

To see if DFMO is safe and effective for HIV positive women who have CIN, a pre-cancerous condition.

About the study:

Women will be screened with a cervical examination, a Pap smear and a colposcopy, including a biopsy if any abnormality is suspected. Women who have biopsy-proven CIN will be enrolled in the study. All women entering this study will take DFMO. DFMO is a liquid which is mixed with another beverage and is taken by mouth. The dose will depend upon the patients' size and weight. Patients will drink DFMO once a day every day for three months. After three months, patients will have another colposcopy performed. There are two screening visits, then study visits once a month. The study lasts about three and a half months.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven (within eight weeks of study entry) CIN, grade II or III

Not allowed:

- Any other active cancers within the last five years
- Women who are pregnant or breastfeeding
- Currently participating in any investigational drug trial

Location:

AIDS Healthcare Foundation
Heather Churchill, RN
(213) 913-3953

50. Oral/Esophageal Candidiasis Treatment: Itraconazole

Title:

ITR-USA-109: An Open-Label, Non-Comparative Trial of Itraconazole Solution for the Treatment of Patients with Oropharyngeal/Esophageal Candidiasis Nonresponsive to Fluconazole

Type of treatment:

Itraconazole: antifungal

Purpose:

To see if itraconazole oral solution is safe and effective for treating oral or esophageal thrush (candidiasis) for patients whose thrush did not get better when taking fluconazole. This study will also provide itraconazole to patients unable to participate in other trials.

About the study:

All patients entering this study will receive open-label (real) itraconazole once a day for four weeks. This form of itraconazole is a liquid and is swallowed. After four weeks, patients either stop taking the drug if their thrush has gotten worse, or continue for two more weeks. After six weeks, patients whose thrush has gone away will continue on a lower dose (3 times a week) indefinitely. All others discontinue the drug.

Required:

- CD4 cell (T-cell) range: not specified
- At least 13 years old
- Oral and/or esophageal thrush (candidiasis)
- Must have failed fluconazole 200 mg/day for a minimum of two weeks

Not allowed:

- Women who are pregnant or breastfeeding
- Liver disease

Location:

Tower Infectious Diseases
Jennifer Ida, PharmD
(310) 358-2300 ext. 228

51. Oral Candidiasis Treatment: rhu GM-CSF, Fluconazole

Title:

001.0009: A Phase II Trial to Evaluate the Safety and Efficacy of Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor (rhu GM-CSF) plus Fluconazole versus Fluconazole Alone in HIV Positive Patients with Oral Candidiasis Resistant or Refractory to Fluconazole

Type of treatment:

Fluconazole: antifungal
GM-CSF: white blood cell stimulator

Purpose:

To compare fluconazole with GM-CSF to fluconazole alone to see which is safer and more effective in treating oral candidiasis (thrush). To see which treatment works best for preventing thrush from coming back.

About the study:

Patients are assigned by chance to receive either fluconazole with GM-CSF or fluconazole alone for 14 days. Fluconazole is a pill and taken by mouth. GM-CSF is given by injection under the skin. Patients will learn to give themselves their own injections. Patients will know which treatment they are receiving. After 14 days, patients taking fluconazole with GM-CSF that have not responded to treatment will be dropped from the study. Patients taking fluconazole alone and have not responded will add GM-CSF to their fluconazole for an additional 14 days. Patients who do respond to treatment will remain on the study until week 10, day 85 or until their thrush comes back or gets worse.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old
- Diagnosis of oral thrush confirmed by stain or culture
- Must be treated with any approved antiretroviral medications for at least one week prior to receiving rhu GM-CSF
- Patients must have received at least 14 days of fluconazole treatment without any clearing of symptoms and this failure must have occured in the month prior to screening for this study

Not allowed:

- Women who are pregnant or breastfeeding
- Use of any other colony stimulating factors while on this study
- Radiation or chemotherapy within two weeks prior to study and throughout the study
- Significant cardiovascular disease, including congestive heart failure, unstable chest pains, heart attack within the past 6 months

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

Kaiser San Francisco - HIV Research Unit
Gretchen Van Raalte, RN, MS
(415) 202-3482

52. Oral Candidiasis Treatment: rhu GM-CSF, Amphotericin B

Title:

A Phase II, Randomized Trial of Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor (rhu GM-CSF) and Amphotericin B versus Amphotericin B Alone in HIV Positive Patients with Refractory Oral Candidiasis

Type of treatment:

Amphotericin B: antifungal
GM-CSF: white blood cell stimulator

Purpose:

To see if GM-CSF, when added with Amphotericin B, is a better treatment for oral candidiasis (thrush) that does not go away by using fluconazole (Diflucan).

About the study:

Patients are assigned by chance to receive Amphotericin B alone or Amphotericin B plus GM-CSF. Amphotericin B is given intravenously (through a vein) over 10-14 days. GM-CSF is given as an injection under the skin every day. All patients will know which medication(s) they are taking. Patients assigned to receive GM-CSF will be taught how to give themselves their own injection of GM-CSF. Study visits are once a week for one month, then every two weeks. The study lasts 12 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old
- Diagnosis of oral candidiasis
- Must have been taking antiretroviral medication(s) for at least one week prior to starting the study
- Must have received at least 14 days of oral fluconazole treatment with no relief of symptoms or clearing of thrush OR have had thrush return after previously being treated with IV Amphotericin B

Not allowed:

- Women who are pregnant or breastfeeding
- Use of radiation or chemotherapy within two weeks of study entry and throughout the study
- Use of any other colony stimulating factors (except erythropoeitin) during the study
- Significant cardiac disease
- Oral candidiasis that did not respond to Amphotericin B in the past

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

53. Oral/Esophageal Candidiasis Treatment: Amphotericin B Colloidal Dispersion

Title:

SEQU-07-32: A Double-Blind, Randomized, Multi-Center Study of the Safety, Efficacy and Toleration of Three Doses of Amphotericin B Colloidal Dispersion (ABCD) versus Amphotericin B in the Treatment of Oropharyngeal Candidiasis (OPC) and Esophageal Candidiasis Failing Azole Therapy in AIDS Patients

Type of treatment:

Amphotericin B: antifungal
Amphotericin B Colloidal Dispersion: anti-fungal

Purpose:

To see which dose of amphotericin B colloidal dispersion (ABCD) is most effective in responding to fluconazole-resistant oral/esophageal candidiasis. To see how ABCD compares to amphotericin B in treatment response. To see how effective ABCD is for maintenance for oral/esophageal candida.

About the study:

Amphotericin B colloidal dispersion (ABCD) is a form of amphotericin B that has been suspended in a solution of fats, which may be better tolerated. For the induction phase, patients are assigned by chance to receive one of three doses of ABCD or to receive amphotericin B. Neither patients nor their doctors will know which drug or which dose they are receiving until the study ends. ABCD and amphotericin B are both given by infusion into a vein. Infusions are given every day for seven days. If needed, patients may receive an additional seven days for a total of 14 days. Patients who respond partially or completely are eligible to for the maintenance phase. They will be assigned by chance to one of two doses of ABCD. Infusions will be once or twice a week and the maintenance phase lasts three months. The study lasts four months.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- Between 1 and 99 years old
- Active oral and/or esophageal candidiasis
- Failure to get better with at least five days of fluconazole therapy. This failure must have occured within six months prior to this episode
- Positive culture for candida

Not allowed:

- Women who are pregnant or breastfeeding
- Known allergy or sensitivity to amphotericin B

- Use of other medications for candidiasis which cannot be discontinued
- Candidiasis that has desseminated to internal organs
- Use of more than 5mg/kg of amphotericin B in the past seven days

Location:

Tower Infectious Diseases
Jennifer Ida, PharmD
(310) 358-2300 ext. 228

New

54. Oropharyngeal Candidiasis Treatment: Fluconazole

Title:

ACTG 323/MSG 40: A Phase III Randomized Study of the Use of Fluconazole as Chronic Suppressive Therapy Versus Episodic Therapy in HIV Positive Subjects With Reccurent Oropharyngeal Candidiasis

Type of treatment:

Fluconazole: antifungal

Purpose:

To find out if it is better to take fluconazole three times a week to prevent thrush or esophageal candidiasis from coming back, or to wait until you get thrush or esophageal *candida* again before taking it.

About the study:

Patients are assigned by chance to take fluconazole three times a week, or to take fluconazole only if they get thrush or esophageal candidiasis. There are no placebos in this study. Patients who join the study when they have thrush or esophageal candidiasis will be treated with fluconazole first, and then assigned by chance to take fluconazole every week, or to wait until they get thrush or esophageal candidiasis again. Study visits are every two months. Blood samples are drawn at each study visit. The study lasts two years.

Required:

- CD4 cell (T-cell) range: 150 or less
- HIV positive
- At least 13 years old
- At least one episode of oropharyngeal candidiasis (thrush) within the past six months

Not allowed:

- Three or more episodes of oropharyngeal candidiasis within the past three months
- Prior esophageal candidiasis
- Women who are pregnant or breastfeeding
- Any fungal infection requiring treatment with amphotericin-B, terbinafine, Lamisil or Ancoban
- Acute or active opportunistic infection requiring treatment

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

UCSF AIDS Program at SFGH / ACTU
David Gary, RN
(415) 476-9296, ext. 354

New

55. Oral Candidiasis Treatment: LY303366

Title:

H4A-MC-XBAC(a): LY303366 Dose-Ranging Efficacy and Safety Study in Oral Candidiasis

Type of treatment:

LY303366: antifungal

Purpose:

To see which of three doses of LY303366 is safest and most effective in the treatment of oral candidiasis (thrush) in HIV-infected patients.

About the study:

Patients are assigned by chance to receive one of three doses of LY303366 OR to receive fluconazole. Neither patients nor their doctors will know which they are receiving until the study ends. Both LY303366 and fluconazole are pills and taken by mouth. There are one to two study visits per week and the study lasts one month.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Presumptive diagnosis of oral candidiasis with positive fungal findings by microscopic examination

Not allowed:

- Patients who have received any systemic antifungal therapy for more than one day within one week of study entry. Does not include troches or "swish and swallow" preparations
- Patients with concurrent fungal infections that would require systemic treatment during the course of the study
- Women who are pregnant or breastfeeding
- Inability to swallow capsules

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, ext. 3763

56. CMV Infection: 1263W94

Title:

CMAA1003: A Phase I/II Trial to Evaluate the Tolerability, Anti-CMV Effect and Pharmacokinetics of 1263W94 Following Multiple Oral Administration of Escalating Doses in HIV-Infected Patients with Asymptomatic CMV Shedding

Type of treatment:

1263W94: antiviral

Purpose:

To see if the new drug 1263W94 is safe and to see if it has any anti-CMV effects. To see how 1263W94 is processed by the body.

About the study:

Patients entering this study will be required to have urine and semen samples tested for CMV. Patients with 100 or less T-cells will also have an eye exam for CMV retinitis. This is a dose escalating study. This means that the first group of patients to enter the study will receive the lowest dose of 1263W94. If no bad side effects are observed, the next group of patients will receive a higher dose and so forth until the highest dose of 1263W94 that researchers plan to study has been given. Patients will know which dose they are receiving. 1263W94 is a pill and is taken by mouth three times a day. On days 1 and 28, patients will be admitted to the hospital for 24 hours. These visits are for timed blood tests. Patients will have a temporary catheter placed in their forearm for these visits. Patients will be treated for 28 days. Study visits are once a week. Patients will return to the clinic four weeks after completing treatment for a final study visit. Patients are paid $410 for completing this study.

Required:

- CD4 cell (T-cell) range: 150 or less
- Viral load range: not applicable
- Male patients only
- At least 18 years old
- HIV positive
- Must be on stable antiretroviral therapy or prophylaxis

Not allowed:

- Active CMV disease, such as retinitis, colitis, encephalitis or pneumonitis
- Vision symptoms of CMV disease such as floaters, decreased visual acuity UNLESS CMV disease is excluded with an eye examination
- Previous therapy with ganciclovir, foscarnet, cidofovir (HPMPC) within two months prior to study entry
- Treatment with interferons, immunomodulators or CMV hyperimmune globulin within one month prior to study entry
- Active hepatitis or other liver diseases
- Gastrointestinal disorders which may interfere with the study such as chronic nausea/vomiting, persistent diarrhea
- Treatment with radiation, chemotherapy within one month of study entry or the need for such during the study
- Known history of lactose intolerance

Location:

Quest Clinical Research, San Francisco
Eileen Glutzer, RN
(415) 353-0800

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

New

57. CMV & HIV Infection: Lobucavir

Title:

Multiple Doses of Oral Lobucavir in AIDS Patients with CMV Viruria and Virosemia

Type of treatment:

Lobucavir: antiviral

Purpose:

To see if lobucavir (BMS-180194) is safe and effective for patients with asymptomatic CMV infection and to see if lobucavir has any activity against HIV.

About the study:

This is a dose escalating study. This means that the first patients to enroll on the study will receive the lowest dose of lobucavir. If no bad side effects are seen, the next group of patients will receive a higher dose, and so forth until the highest dose that researchers plan to study has been given. Lobucavir is a pill and is taken by mouth twice a day for 28 days. Study visits are once a week and patients will be required to give urine and semen specimens at those visits. The study lasts about a month and a half.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Males at least 18 years old
- Positive CMV urine culture and presence of CMV detected in semen

Not allowed:

- CMV retinitis or any CMV disease
- Use of ganciclovir, foscarnet, valaciclovir, cidofovir or any agent with anti-CMV activity within four weeks of study entry
- Any surgery, blood transfusion or use of erythropoietin within four weeks of study entry

- Acute serious illness within four weeks of study entry
- Prior pancreatitis
- Current or recent diarrheal illness, history of malabsorption or recent weight loss
- Positive urine test for drugs of abuse
- Use of any investigational drug within four weeks of study entry
- Female patients

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

58. CMV Neurological Disease: Ganciclovir, Foscarnet

Title:

ACTG 305: A Phase I/II Pilot Treatment Study of CNS Penetration and Response to Ganciclovir and Foscarnet in CMV Neurologic Disease

Type of treatment:

Foscarnet: antiviral
Ganciclovir, IV: antiviral

Purpose:

To see if the combination of ganciclovir and foscarnet is safe and to see how well it penetrates the cerebrospinal fluid (CSF).

About the study:

All patients will receive ganciclovir and foscarnet during an induction phase which lasts 28 days. This induction phase will be followed by a maintenance phase which lasts 20 weeks. Patients who have a clinical relapse when switching to the maintenance phase will re-start the induction phase. Ganciclovir and foscarnet are given by infusion into a vein. They are given every day and the study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 13 years old
- CMV encephalopathy or CMV radiculomyelitis diagnosed within 8 weeks of study entry
- CSF positive for CMV

Not allowed:

- Any active CNS infection or cancer, other than due to CMV
- CSF positive syphilis test
- Varicella-zoster infection within 30 days of study entry
- Known intolerance to both ganciclovir and foscarnet
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

UCSF AIDS Program at SFGH / ACTU
Mary Payne, RN
(415) 476-9296, ext. 356

59. CMV Retinitis Treatment: ISIS 2922 (I)

Title:

ISIS 2922-CS2: A Randomized Comparison of Immediate versus Delayed Treatment with Intravitreal Injections of ISIS 2922 in Patients with Peripheral Cytomegalovirus (CMV) Retinitis

Type of treatment:

ISIS 2922: antiviral

Purpose:

To find out if a new treatment for CMV retinitis, called ISIS 2922, is safe and effective.

About the study:

Patients are assigned by chance to receive either immediate or delayed treatment with ISIS 2922. Patients assigned to delayed treatment will receive ISIS 2922 if their CMV retinitis begins to spread. ISIS 2922 is given by injection into the eye. Injections are given once a week for three weeks, and then once every other week. At each visit, patients will have an eye exam and have blood tests performed. The study lasts 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Diagnosis of CMV retinitis in one eye, previously untreated
- At least 18 years old

Not allowed:

- Certain eye infections or other diseases of the eye
- Patients with retinal detachments
- Previous treatment for CMV retinitis
- Less than 10,000 platelets
- Women who are pregnant or breastfeeding

Location:

AIDS Community Research Consortium
Brenda Cayme, RN
(415) 364-6563

Community Eye Medical Group -
Brian G. Terry, MD
Ramon Bautista
(818) 584-1200

Retina-Vitreous Group - David Boyer, MD
Bridgette Boggess
(310) 854-6201

60. CMV Retinitis Treatment: ISIS 2922, Ganciclovir

Title:

ISIS 2922-CS3: A Randomized Comparison of Intravitreal ISIS 2922 plus Ganciclovir versus Ganciclovir as Treatment for Patients with Cytomegalovirus (CMV) Retinitis

Type of treatment:

Ganciclovir, IV: antiviral
ISIS 2922: antiviral

Purpose:

To test the safety and effectiveness of a new drug called ISIS 2922 in combination with ganciclovir compared to ganciclovir alone for treatment of CMV retinitis.

About the study:

Patients are assigned by chance to receive ISIS 2922 plus ganciclovir or ganciclovir alone. ISIS 2922 is given by injection into the eye. Injections of ISIS 2922 are given every week for three weeks and then every other week until the end of the study. Ganciclovir is given by injection into a vein every 12 hours for 14 days. Patients who receive ganciclovir by injection can have a central line placed so they can receive injections at home. A central line is a small tube (catheter) semi-permanently inserted into a vein, often in the upper chest just below the collar bone. It will be removed at the end of the study. Patients taking ganciclovir will be referred to a home health agency so they can receive ganciclovir injections at home. After 14 days, patients will take ganciclovir tablets until the end of the study. At each visit, patients will have an eye exam and have blood tests performed. The study lasts 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- At least 18 years old
- Diagnosis of CMV which has not improved with other treatments

Not allowed:

- Certain eye infections or other diseases of the eye to be treated
- Patients with retinal detachments
- Prior treatment with ganciclovir implants or treatment with ganciclovir for more than 4 months
- Patients who have had CMV before
- Chronic diarrhea
- Less then 10,000 platelets
- Pregnant or breastfeeding women

Location:

AIDS Community Research Consortium
Brenda Cayme, RN
(415) 364-6563

Community Eye Medical Group -
Brian G. Terry, MD
Ramon Bautista
(818) 584-1200

Retina-Vitreous Group - David Boyer, MD
Bridgette Boggess
(310) 854-6201

61. CMV Retinitis Treatment: ISIS 2922 (2)

Title:

ISIS 2922-CS9: A Randomized Comparison of Two Dosage Schedules of Intravitreal ISIS 2922 for Patients with Advanced Cytomegalovirus Retinitis

Type of treatment:

ISIS 2922: antiviral

Purpose:

To find a safe and effective dose of the new treatment called ISIS 2922 for advanced CMV retinitis.

About the study:

Patients are assigned by chance to receive ISIS 2922 either every other week, or every week for 3 weeks, then every other week until the end of the study. ISIS 2922 is given by injection into the eye. The study lasts 22 weeks. Study visits are every week for the first 3 weeks, then every other week until the end of the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Diagnosis of advanced CMV retinitis in one or both eyes
- At least two previous anti-CMV retinitis therapies
- At least 18 years old

Not allowed:

- Previous ganciclovir implants
- Psuedoretinitis pigmentosa infection
- Syphilis, past or present
- Pregnant or nursing women

Location:

Community Eye Medical Group -
Brian G. Terry, MD
Ramon Bautista
(818) 584-1200

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

Retina-Vitreous Group - David Boyer, MD
Bridgette Boggess
(310) 854-6201

62. CMV Retinitis Treatment: MSL-109

Title:

ACTG 266: A Phase II, Double-Blinded, Randomized, Placebo-Controlled Evaluation of Standard Therapy versus Standard Therapy Combined with Human Monoclonal Anti-CMV Antibody (MSL-109) in the Therapy of AIDS Patients with CMV Retinitis

Type of treatment:

MSL-109: monoclonal antibody

Purpose:

To see if adding MSL-109 to standard CMV retinitis therapy has any effect on the time it takes for CMV disease to get worse. To compare two different doses of MSL-109.

About the study:

Patients should be enrolling on this study at the same time they are starting their first induction dose of IV ganciclovir or foscarnet. Patients will then be assigned by chance to receive one of two doses of MSL-109 or placebo. MSL-109 and its placebo are given by injection into a vein every two weeks. Neither patients nor their doctors will know which medication they are receiving until the study ends. Study visits are every two to four weeks and the study lasts 40 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Newly diagnosed with first episode of CMV retinitis
- At least 13 years old

Not allowed:

- Use of ganciclovir or foscarnet within six months prior to enrollment
- Active opportunistic infections or malignancies requiring treatment that can cause myelosuppression or nephrotoxicity
- Women who are pregnant or breastfeeding
- Diagnosis of CMV disease of any organ in the past
- Current retinal detachment

Location:

LAC-USC Medical Center
Gil Clemente, RN
(213) 343-8284

New

63. CMV Retinitis Treatment: ISIS 2922 (3)

Title:

ISIS 2922-CS7: An Open-Label Study of the Safety and Efficacy of Intravitreal ISIS 2922 in Acquired Immune Deficiency Syndrome (AIDS) Patients With Cytomegalovirus Retinitis (NOTE: Restricted to Patients Who Rollover From Another Controlled ISIS 2922 Trial)

Type of treatment:

ISIS 2922: antiviral

Purpose:

To see if ISIS 2922 is safe and effective for treating CMV retinitis in patients who cannot take or were not helped by ganciclovir and/or foscarnet OR have failed ISIS 2992 therapy on another controlled clinical trial.

About the study:

Patients in this study must rollover from another ISIS 2922 controlled trial. Patients will receive intravitreal injections (injections into the eyeball) of ISIS 2922 at one of two doses depending on the location and severity of their retinitis. There ia a three-week induction period followed by a maintenance period of at least 18 weeks. Induction is given on days 1, 8 and 15 and maintenance doses are given every 14 days, beginning on day 29. The study lasts at least 21 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- CMV retinitis in one or both eyes that was previously treated but is presently uncontrolled
- Not able to take, or unresponsive to other therapies
- Patients must rollover from another ISIS 2922 trial
- At least 18 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Prior surgery to correct retinal detachment
- Past use of ganciclovir implants
- Past or current syphilis

Location:

AIDS Community Research Consortium
Brenda Cayme, RN
(415) 364-6563

Community Eye Medical Group -
Brian G. Terry, MD
Ramon Bautista
(818) 584-1200

Retina-Vitreous Group - David Boyer, MD
Bridgette Boggess
(310) 854-6201

UC Irvine College of Medicine
Karen Lopez
(714) 824-6255

New

64. CMV Retinitis Treatment: VIRACEPT (nelfinavir), Ganciclovir

Title:

AG1343-517: A Randomized, Placebo-Controlled Study to Determine the Effects of VIRACEPT (Agouron Protease Inhibitor) on the Outcome of CMV Retinitis in AIDS Patients who are Receiving Standard Induction and Maintenance Therapy for CMV Infection

Type of treatment:

Ganciclovir, IV: antiviral
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To compare the time of progression of CMV retinitis in patients receiving ganciclovir for their CMV retinitis versus those receiving ganciclovir plus VIRACEPT (nelfinavir).

About the study:

Patients are assigned by chance to receive VIRACEPT in addition to their ganciclovir or to receive placebo with their ganciclovir. Neither patients nor their doctors will know which they are receiving. After three months, all patients will receive open-label (no placebo) VIRACEPT to take in addition to their ongoing ganciclovir treatment. VIRACEPT and its placebo are pills taken by mouth and patients will take nine pills a day. There are two screening visits. Study visits will be every two weeks for the first 12 weeks and will include a dilated eye exam and retinal photograph. After 12 weeks, study visits are once a month. The study lasts 12 months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Newly diagnosed or first relapse of CMV retinitis

Not allowed:

- More than seven days of induction therapy for CMV retinitis

Location:

Harbor-UCLA Medical Center
Crystal Lane, RN
(310) 222-3848

New

65. CMV Retinitis Treatment: Intraocular Cidofovir

Title:

GS-96-503: A Phase I/II, Open-Label, Dose-Escalation Study on the Safety and Efficacy of Intraocular Cidofovir for the Treatment of Relapsing Cytomegalovirus Retinitis in Patients with AIDS

Type of treatment:

Cidofovir: antiviral

Purpose:

To see if injecting cidofovir into the eye is a safe and effective treatment for CMV retinitis.

About the study:

This is a dose escalation study. This means that the first patients to enroll on the study will receive the lowest dose of intravitreal cidofovir. If no bad side effects are seen, the next group will receive a higher dose of cidofovir, and so forth until the highest dose that researchers plan to study has been given. Cidofovir is given as an injection into the eyeball every six weeks. Study visits are every two weeks and the study lasts until CMV retinitis progression.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 13 and 60 years old
- Diagnosis of CMV retinitis

Not allowed:

- CMV disease outside of the eye
- Detached retina repaired by any other means than scleral buckle or laser
- Prior therapy with systemic or intraocular cidofovir

Location:

Quest Clinical Research, San Francisco
Eileen Glutzer, RN
(415) 353-0800

New

66. CMV Retinitis Treatment: RS-79070, IV Ganciclovir

Title:

WV15376B: A Randomized, Controlled Comparison of the Safety and Efficacy of RS-79070, an Oral Prodrug of Ganciclovir vs IV Ganciclovir as Induction Therapy for the Treatment of Newly Diagnosed Peripheral Cytomegalovirus Retinitis

Type of treatment:

RS-79070: ganciclovir prodrug

Purpose:

To see if the ganciclovir prodrug RS-79070 is safe and effective when used as induction therapy in patients with newly diagnosed CMV retinitis. To see how RS-79070 affects the way ganciclovir is processed by the body and to see how RO-79070 affects CMV viral load.

About the study:

Patients with newly diagnosed CMV retinitis will be assigned by chance to receive either IV ganciclovir or RS-79070 for four weeks. IV ganciclovir is given by infusion into a vein. RS-79070 is a pill and taken by mouth. Patients will know which treatment they are receiving. Patients assigned to receive IV ganciclovir will have a small tube (catheter) semi-permanently inserted into a vein in their upper chest to receive drug. After four weeks, all patients will be offered oral RS-79070 for longterm follow-up. Study visits are once a week for four weeks. The study lasts four weeks but patients may then enroll onto the longterm follow-up study which will have study visits every two weeks until progression of CMV retinitis.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Newly diagnosed with peripheral CMV retinitis

Not allowed:

- Women who are pregnant or breastfeeding
- Past CMV disease, such as retinitis, colitis or esophagitis
- Past surgery to the stomach or small intestine
- Prior use of any anti-CMV treatments such as ganciclovir, foscarnet, cidofovir or any investigational anti-CMV drugs

Location:

Davies Medical Center HIV Institute
Bettina Sporkenbach, RN
(415) 565-6163

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

New

67. CMV Retinitis Treatment: GEM 132

Title:

132-100: An Open-Label, Phase I/II Study of the Safety and Efficacy of Single Escalating Doses of Intraocular GEM 132 in AIDS Patients with Relapsing Cytomegalovirus (CMV) Retinitis

Type of treatment:

GEM 132: antiviral

Purpose:

To see if injecting GEM 132 into the eye is safe and to see if it is effective in treating CMV retinitis.

About the study:

The first group of patients to enter this study will receive the low dose of GEM 132. If no bad side effects are seen, the next group of patients will receive the higher dose. GEM 132 is given as a single injection into the eyeball. Study visits are once a week for the first month, then every two weeks for an additional two months. Eye exams and blood tests will be performed at study visits.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- CMV retinitis that has gotten worse

Not allowed:

- Prior use of ganciclovir implants or intravitreal cidofovir in the eye to be studied

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

68. Cryptococcal Meningitis Treatment: Fluconazole, Liposomal Amphotericin B

Title:

94-0-013: A Randomized, Double-Blind, Comparative Trial of Two Doses of Ambisome (Liposomal Amphotericin-B) Versus Amphotericin B, Followed by Fluconazole in the Treatment of Acute Cryptococcal Meningitis in AIDS Patients.

Type of treatment:

Amphotericin B: antifungal
Amphotericin B, Liposomal: antifungal
Fluconazole: antifungal

Purpose:

To see if the new liposomal formulation of Amphotericin B is safer and more effective than the older version in treating cryptococcal meningitis. To find out which dose of the new formulation is better.

About the study:

This study is testing a new formulation (called "liposomal") of the drug amphotericin B. The liposomal formulation means that the drug is packaged in fat molecules, which makes higher doses easier to tolerate. Fat molecules are also harder for the body to process, so the drug is not passed as quickly as in a non-liposomal version. This study is also a dose finding study, which means that the first group of people to join will receive a smaller dose of liposomal amphotericin B. If this dose is found to be safe, the next group will receive a higher dose. In this study, people are assigned by chance to receive either the new liposomal formulation or the standard formulation. Neither the patients nor their doctors will know which they are receiving until the study ends. Those on the standard formulation receive fluconazole for 8 weeks after two weeks of amphotericin B treatment.Both formulations of Amphotericin B are given as an infusion into a vein. Fluconazole is a pill. Samples of cerebrospinal fluid (CSF) will be taken. A tube is inserted between the bones of the spine in the lower back to collect a sample of CSF. The total length of the study is ten weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: unspecified
- Acute cryptococcal meningitis
- HIV positive
- Greater than 1 month old

Not allowed:

- Other systemic fungal infection at time of study entry
- History of anaphylaxis (severe allergic reaction) to amphotericin B
- Pregnant or nursing women

Location:

Beer Medical Group
Heather Robertson
(213) 937-5151

Kaiser San Francisco - HIV Research Unit
Gretchen Van Raalte, RN, MS
(415) 202-3482

UCSF AIDS Program at SFGH/ICTG
Nelson Murcar, RN
(415) 476-9296, ext. 333

69. HIV Dementia Treatment: Delavirdine

Title:

A Phase II, Placebo-Controlled Study of Delavirdine Mesylate (DLV) for Treatment of AIDS Dementia Complex (ADC)

Type of treatment:

Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)

Purpose:

To find out if the antiviral delavirdine can help improve neurological (brain and nervous system) function in people with AIDS Dementia Complex.

About the study:

This is the first trial studying DLV's effectiveness as a treatment for AIDS Dementia Complex (ADC). Patients are first divided into groups by whether or not they are currently taking antiretrovirals. People who are taking antiretrovirals are assigned by chance to receive delavirdine pills or placebo pills in addition to their current treatments. In this group, neither patients nor their doctors will know which they are taking until the study ends. Patients who cannot take antiretrovirals are all given delavirdine. The study lasts 12 weeks and involves three lumbar punctures (spinal taps). At the end of twelve weeks participants may be offered a supply of delavirdine.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 14 years old
- AIDS-related dementia

Not allowed:

- Women who are pregnant or breast-feeding
- Active opportunistic infection
- Systemic chemotherapy
- Active toxoplasmosis, CNS lymphoma, PML, meningitis

Location:

LAC-USC Medical Center
Irene Teran, RN
(213) 343-8285

70. AIDS Dementia Treatment: 1592U89

Title:

CNAB 3001: A Phase III, Randomized, Double-Blind, Multicenter Study to Evaluate the Safety and Efficacy of 1592U89 in HIV-1 Infected Patients with AIDS Dementia Complex Receiving Antiretroviral Therapy Either Approved or Expanded Access

Type of treatment:

1592U89: antiretroviral

Purpose:

To see if 1592U89 is safe, well-tolerated and to see if it can improve thought processes in patients with AIDS-related dementia.

About the study:

Patients are assigned by chance to receive 1592U89 or placebo. 1592U89 and its placebo are pills taken by mouth. Neither patients nor their doctors will know which they are taking until the study ends. After 12 weeks of treatment, patients will be offered open label (real) 1592U89 for an additional 40 weeks. Study visits are every two weeks for the first 12 weeks. After 12 weeks, patients participating in the open label portion of the study will have study visits every 2-4 weeks for the first eight weeks, then every 8 weeks for the remainder of the study. The study lasts 52 weeks. Patients are required to have a lumbar puncture (spinal tap) at the beginning of the study. Patients will be paid $100 for each spinal tap after the first one. Patients will also be paid $25 for each follow-up visit..

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- Between 18 and 65 years old
- HIV positive
- Documented diagnosis of AIDS Dementia Complex
- Must be stable on current antiretroviral treatment for at least 8 weeks prior to study entry

Not allowed:

- Use of d4T is not allowed during this study
- Patients who currently have CNS infections or cancers
- Previous neurological disease unrelated to HIV such as multiple sclerosis, stroke, degenerative disease which may interfere with neurological testing

- Alcohol or illicit drug use which could interfere with the study
- Hepatitis or pancreatitis in the past 6 months
- Women who are pregnant or breastfeeding
- Use of radiation or chemotherapy within one month of study entry (or the need for such during the next 12 weeks)
- Use of any investigational antiretroviral trial or HIV vaccine trial in the past 3 months
- Use of immunomodulators, such as steroids, interleukins, thalidomide or interferons within the past month
- Use of nerve growth factor

Location:

UCSF AIDS Program at SFGH/ICTG
Nelson Murcar, RN
(415) 476-9296, ext. 333

71. AIDS Dementia Complex Treatment: Memantine

Title:

ACTG 301: A Phase II, Randomized, Double-Blind, Placebo-Controlled Trial of Memantine for AIDS Dementia Complex (ADC) As Concurrent Treatment with Antiretroviral Therapy

Type of treatment:

Memantine: antiviral

Purpose:

To see if memantine has any effect on improving AIDS Dementia Complex. To see if memantine may have any effect on relieving painful peripheral neuropathy in patients being treated with antietroviral therapy.

About the study:

Patients will be assigned by chance to receive memantine or placebo to take with their current antiretroviral treatment(s). Neither patients nor their doctors will know which they are taking until the study ends. Memantine is a pill and taken by mouth. In addition to the screening process, there are eight study visits, once a month. The study lasts 16 weeks. After 16 weeks, all patients will be offered real memantine (no placebo) for an additional 12 weeks. There are two lumbar punctures (spinal taps) required; one at screening, the second at 16 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of AIDS Dementia Complex (ADC), stage 1, 2, or 3
- Must be on stable antiretroviral treatment for at least eight consecutive weeks prior to study entry AND maintain this treatment throughout the study
- Impaired cognitive function as evidenced by neuropsychological tests

Not allowed:

- Any cancers other then basal cell, cervical or KS of the skin
- Any psychiatric diagnosis, such as schizophrenia or severe bipolar illness, which may affect the analysis of the study
- Active AIDS-defining opportunistic infections
- Neurologic disease unrelated to HIV, such as multiple sclerosis, stroke, degenerative disease
- Seizure disorder
- CNS infections or neoplasms, such as toxoplasmosis, CNS lymphoma, PML, cryptococcal meningitis, untreated syphilis
- Women who are pregnant or breastfeeding
- Active alcohol or drug abuse which may interfere with the study
- Use of IV Pentamidine or use of calcium channel antagonists (high blood pressure medications) within 30 days prior to study entry

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

UCSF AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

UCSF AIDS Program at SFGH/ACTU
Kathy Dybeck, RN
(415) 476-9296 ext. 353

72. Diarrhea Treatment: Octreotide

Title:

Continuous Subcutaneous Administration of Octreotide for Refractory AIDS-Associated Diarrhea

Type of treatment:

Octreotide: digestive hormone

Purpose:

To find out if giving octreotide continuously (all day, instead of a few times a day) is more effective in relieving diarrhea that does not respond to (or comes back after) other treatments.

About the study:

All patients receive the treatments Pancrease MT16 and Octreotide. Pancrease MT16 is an enzyme supplement that will help the body tolerate octreotide better. Everyone must keep a diary of their bowel movements every day of the study. On certain days, you will be asked to weigh your bowel movements with special equipment provided by the study. After one week of taking Pancrease MT16 pills, you will be shown how to give yourself subcutaneous infusions of octreotide. These are given using a pump and a small tube that is attached to a small needle that is inserted under the skin of your abdomen (stomach area). The dose of octreotide is increased each week for three weeks,

for a total of four weeks. Participants are reimbursed $500 for completing the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old
- Diarrhea of a certain quantity for at least two weeks in a row
- If diarrhea is due to parasites such as *cryptosporidium*, *Isospora belli*, or microsporidia, participants must either be on stable treatment, or no treatment at all, and must agree not to change treatment during the study.

Not allowed:

- Diarrhea due to a treatable cause
- Active CMV of the gastrointestinal tract
- History of ulcerative colitis or Crohn's disease
- Gallstone disease
- Pregnant women

Location:

San Francisco General Hospital GI Clinic
Amy Auslander
(415) 206-4746

73. *Cryptosporidium* Diarrhea Treatment: Bovine Immunoglobulin Concentrate

Title:

GC-10-09: A Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Phase II Study of the Safety and Efficacy of Bovine Immunoglobulin Concentrate in the Treatment of Diarrhea Associated With *C. parvum* Infection in Adult Patients With AIDS

Type of treatment:

BIC: immune modulator

Purpose:

To learn if Bovine Immunoglobulin Concentrate (an antibody derived from cows) is an effective treatment for *cryptosporidium* diarrhea.

About the study:

Patients are assigned by chance to receive BIC or placebo for the first four weeks of the study. BIC and its placebo is a powder which is mixed with water and swallowed. Neither patients nor their doctors will know which they are receiving until the study ends. After four weeks, patients may receive open-label (real) BIC for an additional 12 weeks. The study lasts 16 weeks and there are six study visits.

Required:

- CD4 (T-cell) range: 180 or below
- HIV positive
- At least 18 years of age
- Stool positive for Cryptosporidium

Not allowed:

- Women who are pregnant or nursing
- CMV colitis or enteritis
- Microsporidia or other stool pathogens
- Lactose intolerant

Location:

San Francisco General Hospital GI Clinic
Amy Auslander
(415) 206-4746

Tower Infectious Diseases
Jennifer Ida, PharmD
(310) 358-2300 ext. 228

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

74. Diarrhea Treatment: Questran, ADEK

Title:

H7531-12449-01: A Study Evaluating Bile Acid Malabsorption and the Use of Cholestyramine in HIV-Associated Diarrhea

Type of treatment:

ADEK: vitamins
Questran: cholesterol lowering agent

Purpose:

To see if cholestyramine (Questran) is effective in controlling HIV-related diarrhea cause by bile acid malabsorption and/or an overgrowth of bacteria in the small bowel.

About the study:

Patients entering this study must have diarrhea that is not caused by any treatable organism. All patients will have an endoscopy, which is a small tube inserted into the throat to examine the upper digestive tract and to have a sample of fluid removed from part of the small intestine. Patients will also have a sigmoidoscopy, which is a tube inserted into the rectum to examine the lower intestinal tract. All patients will also have a breath study to see if they have bile acid malabsoprtion. After completing all these tests, patients will follow a diet of 100 grams of fat per day. During this period, patients will record all bowel movements during seven consecutive days. On days 4 to 7, they will collect all bowel movements in a container provided for this purpose and, at the end of the seven-day period, will bring in the collected stool for analysis. Patients will then take Questran (cholestyramine) for seven days. Questran is a powder which is mixed with water and taken orally. Patients will take Questran three times a day just before meals. Patients will follow the same diet and stool collection as before. Patients will also take

one tablet of ADEK, a mulitvitamin containing Vitamins A, D, E, and K to prevent malnutrition. Study visits are once a week and the study lasts 6 - 8 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- At least 18 years old
- HIV positive
- HIV-associated diarrhea for which an endoscopic evaluation is considered necessary.
- Positive testing for fecal fat

Not allowed:

- Diarrhea caused by known treatable pathogens, such as parasites, amoebas
- Current active opportunistic infections requiring systemic treatment. Oral candidiasis (thrush) and KS are allowed.

Location:

Division of Gastroenterology at SFGH
Johannes Koch, MD
(415) 206-4753

New

75. Diarrhea Treatment: Chinese Herbs

Title:

CC 027: A Pilot Study of Chinese Herbs in HIV-Associated *Cryptosporidium*-Negative Diarrhea

Type of treatment:

Chinese Herbs: Chinese Medicine

Purpose:

To see if taking a Chinese herbal medication is safe and effective in reducing the number of stools per day related to HIV-associated *Cryptosporidium*-negative diarrhea.

About the study:

Patients will receive a Chinese herbal medication called Source Qi. Source Qi is a tablet and taken by mouth. Patients will take a minimum of 12 up to a maximum of 20 tablets a day. The study lasts eight weeks. Study visits will be conducted at baseline, and at weeks 2, 4, and 8 for evaluation of symptoms and side effects. Blood tests will be done at weeks 4 and 8. Stool samples will be collected at the beginning of the study. Patients will be required to keep a daily stool diary.

Required:

- CD4 cell (T-cell) range: not specified
- At least 17 years old
- HIV positive
- Chronic diarrhea defined as three or more loose stools per day for at least 14 days
- Baseline stool sample negative for treatable parasites including *Cryptosporidium*

Not allowed:

- Any hospital admission within a month prior to study entry
- Documented allergies to Chinese herbs
- Stools containing blood which can be seen by the patient
- Fevers above 101 F for greater than seven days
- Alternating constipation/diarrhea
- Any history of a *Cryptosporidium*-positive stool

Location:

Community Consortium
To be arranged through physician-see page 105
(415) 476-9554

Quan Yin Healing Arts Center
Carla Wilson
(415) 861-4964

New

76. Cryptosporidiosis Treatment: Nitazoxanide

Title:

ACTG 336: A Phase II/III Placebo-Controlled Study of Nitazoxanide for Persons with AIDS and Cryptosporidiosis

Type of treatment:

Nitazoxanide: antiparasitic

Purpose:

To see if nitazoxanide (NTZ) is an effective treatment for cryptosporidiosis, disease caused by a parasite that infects the intestines of people.

About the study:

Patients are assigned by chance to receive NTZ or placebo for three weeks. Neither patients nor their doctors will know which they are receiving until the study ends. At three weeks, all patients will receive NTZ for another three weeks. At six weeks, patients whose diarrhea has improved will be assigned by chance to receive a lower or higher dose of NTZ. Patients whose diarrhea has not improved or gets worse may receive a higher dose of NTZ. NTZ is taken by mouth. Study visits are once a week for the first month, then approximately once a month. The study lasts approximately eight months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Intestinal cryptosporidiosis with diarrhea producing at least four stools per day for at least 21 of the last 28 days

Not allowed:

- Patients unable to tolerate oral medications
- Diarrhea due to any other treatable cause
- Any additions or changes to antiretroviral medications within four weeks of study entry
- Prior use of nitazoxanide
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH / ACTU
David Gary, RN
(415) 476-9296, ext. 354

77. Hepatitis A Prevention: Vaccine

Title:

A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Immunogenicity of HAVRIX in Subjects With HIV Infection

Type of treatment:

HAVRIX: vaccine, hepatitis A

Purpose:

To see if HAVRIX, a hepatitis A vaccine, is safe and effective in preventing hepatitis A infection in people with HIV.

About the study:

Patients will be assigned by chance to receive vaccine or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. HAVRIX is given twice by injection under the skin. Study visits will occur once a month. Patients will be on this study indefinitely.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive

Not allowed:

- Pregnant or nursing women
- Active HIV-related opportunistic infections
- Chronic diarrhea or wasting syndrome
- Chemotherapy or immune-modulating drugs

Location:

California Infectious Disease Associates
Carol Kane, RN-B
(800) 910-2432

Santa Clara Valley Medical Center
Carol Kane, RN-A
(408) 885-4316

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

78. Chronic Viral Hepatitis Treatment: Acupuncture

Title:

HIV/Chronic Viral Hepatitis Acupuncture Research Program

Type of treatment:

Acupuncture: Chinese medicine

Purpose:

To find out if acupuncture is an effective treatment for chronic viral hepatitis.

About the study:

Patients are assigned by chance to receive traditional Chinese acupuncture, traditional Korean acupuncture, or no acupuncture. Patients do not know if they are getting Chinese or Korean acupuncture until the study ends. Patients receive acupuncture twice a week for four months.

Required:

- CD4 cell (T-cell) range not specified
- HIV positive
- Diagnosis of chronic viral hepatitis
- At least 18 years old
- English or Spanish speaking

Not allowed:

- AIDS
- Currently taking other treatment for chronic viral hepatitis

Location:

Quan Yin Healing Arts Center
Carla Wilson
(415) 861-4964

79. Histoplasmosis Treatment: AmBiSome, Amphotericin B

Title:

A Phase IIB Study to Compare the Safety and Efficacy of AmBisome with Conventional Amphotericin B for Induction Therapy of Histoplasmosis in Patients with AIDS

Type of treatment:

AmBisome: antifungal
Amphotericin B: antifungal

Purpose:

To see if the new liposomal formulation of Amphotericin B is safer and more effective than the older formulation in treating moderate to severe histoplasmosis. AmBisome is Amphotericin B that has been packaged in fat molecules, which makes higher doses easier to tolerate.

About the study:

Patients will be assigned by chance to receive AmBisome or Amphotericin B. Both medications are given as an infusion into a vein. Neither patients nor their doctors will know which they are taking until the study ends. Patients will receive study medication for two weeks. After the two weeks of induction therapy, all patients will then take

oral itraconazole daily for ten weeks. The study lasts 12 weeks. Induction therapy can be stopped after a minimum of seven days for those patients who respond well to treatment.

Required:

- CD4 cell (T-cell) range: not specified, HIV positive
- At least 18 years old
- Evidence of disseminated histoplasmosis

Not allowed:

- Known allergy to amphotericin B
- Any other active opportunistic infection
- Pregnant or nursing women

Location:

UCSF AIDS Program at SFGH/ICTG
Nelson Murcar, RN
(415) 476-9296, ext. 333

80. Herpes Simplex Prevention: Acyclovir

Title:

A Study to Determine the Effect of Acyclovir Treatment for Prevention of Herpes Simplex Virus (HSV) Infection and its Effect on HIV Viral Load

Type of treatment:

Acyclovir: antiviral

Purpose:

To see if treatment with acyclovir can prevent herpes simplex lesions from coming back in patients that have had herpes infections in the last year. To see what effect acyclovir has on HIV viral load.

About the study:

Patients are assigned by chance to receive four acyclovir pills a day or to receive four placebo pills a day. Neither patients nor their doctors will know which they are taking until the stdy ends. There are two screening visits to the study. Patients must return to the clinic weekly for blood tests and herpes cultures. Patients will be paid for participating in this study. If patients develop a herpes outbreak while on this study, they will be asked to join the herpes treatment study, on which they will receive open-label (real) acyclovir. The study lasts 12 weeks.

Required:

- CD4 cell (T-cell) range: Less than 250
- HIV positive
- Must have had a herpes simplex (oral, genital or anorectal) outbreak more than two months but less than one year prior to study entry

Not allowed:

- Current herpes lesions
- Use of acyclovir, foscarnet, or ganciclovir within one month before study entry

Location:

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

81. Herpes Simplex Treatment: Acyclovir

Title:

A Study for the Treatment of Herpes Simplex Outbreaks with Acyclovir and its Effects on HIV Viral Load and Other Immune Characteristics

Type of treatment:

Acyclovir: antiviral

Purpose:

To observe HIV viral loads and other characteristics of immune activation in people that are having an outbreak of herpes simplex (oral, genital or rectal) and are treated with acyclovir.

About the study:

Patients will be treated with five pills of acyclovir a day for ten days or until their herpes lesions have healed. Patients will return to the clinic on days five and ten, at the end of their treatment and at weeks two, four, eight and twelve after the end of their treatment. Blood tests will be done at every visit and herpes cultures will be done at every other visit. Patients will be paid for completing this study. After patients have completed the follow-up period, they may enter the herpes simplex prevention study.

Required:

- CD4 cell (T-cell) range: Less than 250
- HIV positive
- Herpes simplex lesion(s) of the mouth, genitals or anorectal regions. Lesions will be cultured by the research staff

Not allowed:

- Patients with a negative herpes simplex culture
- Use of acyclovir, foscarnet or ganciclovir within one month of study entry

Location:

Harbor-UCLA Medical Center
Sandra Houston, LVN
(310) 222-5291

82. Genital Herpes Treatment: Famciclovir

Title:

BRL-42810: An Open-Label Study to Evaluate Oral Famciclovir for the Suppression of Recurrent Genital Herpes in HIV-Infected Patients

Type of treatment:

Famciclovir: antiviral

Purpose:

To see if oral famciclovir is safe and effective in treating genital herpes infections in HIV-infected people and to collect data on the clinical activity of recurrent genital herpes.

About the study:

All patients will receive oral famciclovir pills to be taken twice a day. There are no placebos used in this study. In addition to the screening and follow-up visits, there will be study visits once a month for 16 weeks. The study lasts seven months.

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- At least 18 years old
- HIV positive
- Active genital herpes simplex or a history of recurrent genital herpes (one or more episodes) for which the investigator feels supressive treatment is warranted

Not allowed:

- Use of a systemic antiherpes treatment or applied a topical antiviral to the genital region within 14 days prior to study entry
- Use of systemic corticosteroids within the past month or during the study
- Use of any investigational drug or vaccine within 30 days prior to study entry
- Women who are pregnant or breastfeeding
- Known hypersensitivity to acyclovir
- Any spreading of the herpes to internal organs
- Any other genital tract infections or disorders which would interfere with the study
- Active alcohol or substance abuse which could interfere with the study

Location:

LAC-USC Medical Center
Irene Teran, RN
(213) 343-8285

UCSF AIDS Program at SFGH/ICTG
Kory McGuire
(415) 476-9296 ext. 307

New

83. Herpes Simplex: Observational

Title:

Multisite Antiviral Resistance Studies Pilot Surveillance for Acyclovir-Resistant HSVII

Type of treatment:

Observational: none

Purpose:

To determine the extent of acyclovir-resistant herpes simplex. To collect and store specimens of acyclovir-resistant genital herpes simplex for in-depth lab studies.

About the study:

Patients joining this study will have one study visit where a herpes swab will be taken and patients will fill out a questionnaire. This study is limited to patients who have peri-anal or rectal herpes.

Required:

- Herpes simplex lesion in the peri-anal or rectal area

Location:

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, ext. 3763

New

84. Herpes Simplex (peri-anal) Treatment: SP-303, Acyclovir

Title:

SP-303T-A-04: Double-Blind Placebo - Controlled Study to Compare the Combination of 15% SP-303 Gel with Acyclovir versus Acyclovir Alone for the Treament of Recurrent Herpes Simplex Virus (HSC I V) Infections in Subjects with Acquired Immune Deficiency Syndrome

Type of treatment:

SP-303: antiviral gel

Purpose:

To compare the effectiveness of SP-303 in combination with acyclovir to acyclovir alone for the treatment of anogenital herpes simplex infections.

Study Description:

Patients are assigned by chance to recieve SP-303 or placebo gel to take with oral acyclovir. Neither patients nor their doctors will know which they are receiving until the study ends. All patients will take acyclovir. Acyclcovir is a pill is taken by mouth. SP-303 and its placebo are a gel which is applied onto herpes lesions. Study visits are approximately every other day for the first two weeks with a final study visit at week 4. The study lasts 28 days.

Required:

- CD4 cell (T-cell) range not applicable
- At least 18 years old
- HIV positive

- Documented recurrent (at least one prior episode) of perineal (genital, perianal and neighboring areas) herpes simplex virus infection
- Current infection must be less than 3 days old at study entry
- Stable antiretroviral therapy (if any) for at least the past two weeks prior to study entry

Not allowed:

- Prior episodes of herpes simplex which failed acyclovir treatment
- Treatment with any other anti-herpes medication within the past five days prior to study entry
- Active internal or rectal herpes
- Women who are pregnant or breastfeeding
- Use of any immunomodulators within 30 days prior to study entry
- Previous use of SP-303

Location:

ViRx Inc.
Debbie Hildebrandt
(415) 353-5623

85. KS Treatment: Tretinoin

Title:

A Multicenter, Phase II/III Study of AR-623 (Tretinoin I.V.) in Patients with AIDS-Associated Kaposi's Sarcoma

Type of treatment:

Tretinoin: skin cell growth stimulant

Purpose:

To find out if AR-623 is a safe and effective treatment for Kaposi's sarcoma. To find out the highest dose of AR-623 patients can safely take. To learn how AR-623 is absorbed and processed in the body.

About the study:

This is a dose-finding study. This means that the first patients who join the study are given the lowest dose of AR-623. If there are no bad side effects the next patients enter the study at a higher dose level. This plan is followed until the highest dose is found that does not cause bad side effects. AR-623 is given by infusion into a vein, either one or three times per week. The study lasts 24 to 32 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Kaposi's sarcoma of the skin (diagnosed using a biopsy)
- At least 18 years old

Not allowed:

- Other chemotherapy, immune therapy, hormone therapy or radiation therapy within two weeks of starting the study
- Kaposi's sarcoma of the internal organs which causes pain or other symptoms
- Active opportunistic infection within three weeks of starting study (except candidiasis)
- Diabetes
- Cancer other than KS
- Women who are pregnant or nursing

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

86. KS Treatment: ddI, Alpha Interferon

Title:

ACTG 206: Open-Label, Phase II Study with Randomization to One of Two Doses of IFNa-2b Combined with ddI Daily

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Interferon, alpha: immune modulator

Purpose:

To find out if it is safe for people with Kaposi's sarcoma to take a combination of the drugs alpha interferon and ddI. To find out if taking this combination of drugs is helpful in treating Kaposi's sarcoma. To learn about the effects of this combination of drugs on the immune system.

About the study:

Everyone in this study takes the same dose of ddI twice per day. In addition, patients are assigned by chance to take one of two doses of alpha interferon. No one takes placebo. Alpha interferon is injected under the skin. Patients learn to inject themselves, so they may take the medicine at home. Patients are in the study for an indefinite length of time, depending on response to treatment. After 16 weeks of treatment, patients may take any FDA-approved antiretroviral therapy in addition to ddI and alpha interferon.

Required:

- CD4 cell (T-cell) range: not specified
- AIDS
- Kaposi's sarcoma of the skin, lymph nodes or roof (hard palate) of the mouth
- At least 12 years old

Not allowed:

- Any opportunistic infection, now or in the past
- Kaposi's sarcoma of the internal organs
- Severe swelling caused by Kaposi's sarcoma
- Treatment with alpha interferon in the past
- Unable to take ddI because of side effects
- Cancer chemotherapy, radiation therapy, or drugs intended to increase or decrease the function of the immune system within 30 days before starting the study

Location:

Kaiser San Francisco - HIV Research Unit
Gretchen Van Raalte, RN, MS
(415) 202-3482

87. KS Treatment: Tin Ethyl Etiopurpurin

Title:

A Phase III Study of Tin Ethyl Etiopurpurin Photodynamic Therapy of AIDS-Related Kaposi's Sarcoma

Type of treatment:

Tin Ethyl Etiopurpurin: anti-KS

Purpose:

To see if Tin Ethyl Etiopurpurin combined with a laser light beam is an effective way to treat KS lesions.

About the study:

All patients receive one injection of Tin Ethyl Etiopurpurin. KS lesions will be treated with a laser light beam. The study lasts for six months and requires five study visits.

Required:

- CD4 cell (T-cell) range: not specified
- Kaposi's Sarcoma of the skin
- At least 18 years old

Not allowed:

- Greater than 50 KS lesions
- Pregnant or nursing women
- Active opportunistic infections
- Known photosensitivity
- History of lupus erythematosus
- Systemic chemotherapy or interferon in the last 30 days

Location:

UCSF/SFGH Dermatology
Pat Brown, RN
(415) 476-9219

88. KS Treatment: Topotecan

Title:

SKF 104864-4: An Open, Non-Comparative, Phase II Study of Topotecan, Given as a Continuous 21-day Infusion Every 28 Days, to Patients with Kaposi's Sarcoma

Type of treatment:

Topotecan: chemotherapy, systemic

Purpose:

To learn whether and how quickly AIDS-related KS gets better with treatment with Topotecan.

About the study:

All patients receive treatment with Topotecan. Topotecan is given as an infusion into a vein, and participants will need to have a "PIC line" inserted. A PIC line is a small tube (catheter) semi-permanently inserted into a vein in the arm. Treatments are given through this tube at home every day for 21 days. All participants go through at least two 21 day treatments, given 4 weeks apart. Patients must come to the clinic weekly to get more drug to infuse at home.

Required:

- CD4 cell (T-cell) range: above 50
- HIV positive
- At least 18 years old
- KS that got worse after treatment with at least 2 different kinds of chemotherapy
- At least 3-5 KS lesions that can be measured

Not allowed:

- More than 2 prior chemotherapy regimens
- KS that has spread to the lungs
- Extensive radiation within last 2 weeks
- Serious opportunistic infection requiring acute therapy (long term MAC treatment is allowed)
- Pregnant or breastfeeding women

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

89. KS Treatment: Liarozole

Title:

LIA-USA-34: A Pilot, Phase II Study of Liarozole in Kaposi's Sarcoma

Type of treatment:

Liarozole: chemotherapy

Purpose:

To see if the new drug, liarozole is a safe and effective treatment for KS lesions.

About the study:

This is a dose-escalating study. This means that the first ten patients to enroll on the study will take 150 mg of liarozole twice a day. The second ten patients to enroll will take 150 mg of liarozole twice a day for two weeks, then take 300 mg of liarozole twice a day. Liarozole is a pill and is taken by mouth. Treatment will last 48 weeks and study follow-up will last for six months.

Required:

- CD4 cell (T-cell) range: at least 50 or above
- HIV positive
- At least 18 years old
- Biopsy-proven KS skin lesions and at least one lesion that has not been treated with local therapy

Not allowed:

- Pulmonary KS
- Female patients
- Ongoing therapy for infections (preventive medicine for PCP or MAC is allowed)
- Active infections
- Other cancers
- Use of chemotherapy, radiation or immune modulators within 30 days of study entry
- Active substance abuse

Location:

AIDS Community Research Consortium
Mari Steeno, RN
(415) 364-6563

AIDS Oncology Practice at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 885-7252

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

UCSF AIDS Program at SFGH/ICTG
Dorie Heeren, RN
(415) 476-9296, ext. 305

90. KS Treatment: Paclitaxel

Title:

1X-110-081: Paclitaxel in Advanced Refractory Kaposi's Sarcoma: A Phase II Trial of Paclitaxel from Baker Norton Pharmaceuticals

Type of treatment:

Paclitaxel: chemotherapy

Purpose:

To see if paclitaxel is safe and effective in treating advanced KS lesions.

About the study:

All patients will receive paclitaxel every two weeks. Paclitaxel is given by infusion into a vein. Infusions last about three hours. The study will last 20 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- Advanced KS lesions, defined as: at least 25 or more skin lesions; internal organ involvement; symptomatic edema (swelling)
- At least 18 years old
- Must have had at least one systemic chemotherapy treatment which failed to provide any benefit

Not allowed:

- Systemic chemotherapy within two weeks of study entry
- Women who are pregnant or breastfeeding
- Other cancers
- Current serious infections
- Any chest pains or heart attack in the past six months
- Any prior use of Paclitaxel

Location:

LAC-USC Medical Center
Miki Ilaw, RN
(213) 343-8271

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

91. KS Treatment: ALRT1057

Title:

Randomized, Phase III, Vehicle-Controlled Trial of ALRT1057 Topical Gel in Patients with AIDS-Related Cutaneous Kaposi's Sarcoma

Type of treatment:

ALRT1057: anti-KS

Purpose:

To see if ALRT1057 is a safe, well-tolerated and effective treatment when applied to KS lesions.

About the study:

Patients are assigned by chance to receive ALRT1057 gel or placebo gel. The gel is applied to KS lesions three times a day. After 12 weeks, all patients will receive open-label (real) ALRT1057 gel for their KS lesions. Study visits are every two weeks for the first four weeks, then every four weeks. As long as the study remains open and active, patients may continue open label therapy if they feel it is a benefit.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- KS lesions of the skin (minimum of 6 lesions)
- At least 18 years old

Not allowed:

- Systemic or topical treatment of lesions within 30 days before the study
- Any current, serious infections
- Women who are pregnant or breastfeeding
- Any known allergies to retinoid drugs

Location:

Center for Special Immunology - Irvine
Sandra Casserella, RN
(714) 753-0670

Center for Special Immunology - San Diego
Norm Robert, LVN
(619) 291-1122

Desert AIDS Project
Juan Casillas
(619) 323-2118 ext. 235

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

HIVCare, Saint Francis Memorial Hospital
Sher Vieira
(415) 353-6215

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Kraus Medical Partners
Cristina Dawes
(213) 930-2324

LAC-USC Medical Center
Suzanne Cabriales, RN
(213) 343-8270

Marcus Conant, MD Clinical Research
Kurtis Opp, PA
(415) 661-2613

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

92. KS Treatment: ALRT1057 (2)

Title:

LGD1057-503-00: A Randomized, Double-Blind, Placebo-Controlled 12-Week Clinical Trial of Topical 9-cis-Retinoic Acid Gel (ALRT1057) in the Palliative Treatment of Cutaneous AIDS-Related Kaposi's Sarcoma

Type of treatment:

ALRT1057: anti-KS

Purpose:

To see if ALRT1057 gel is a safe and effective treatment for Kaposi's sarcoma lesions.

About the study:

Patients will be assigned by chance to receive ALRT1057 gel or a placebo gel. The gel will applied to KS lesions twice a day. Patients will be free to treat any lesion which they can medicate themselves up to a maximum of eight lesions. These lesions will be measured and photographed by the research staff. After 12 weeks, all patients will be offered open-label (real) ALRT1057 gel. Study visits will occur at weeks two, four, eight and twelve. Those patients who wish to continue treatment after week 12 will be provided medication in an open-label follow-up protocol.

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- HIV positive
- At least 18 years old
- At least three (3) biopsy-proven KS lesions of the skin which are in a location that can be treated with topical gel

Not allowed:

- Women who are pregnant or breastfeeding
- Any systemic treatment for KS within the previous four weeks
- Any previous local therapy to any study lesion
- No current enrollment or participation in the last 30 days in any investigational treatment for KS
- Current infections requiring medication
- Any other cancers of internal KS requiring systemic treatment during the course of the trial
- Prior treatment with Vitamin A or any other retinoid class drug

Location:

Davies Medical Center HIV Institute
Trisha Harasty
(415) 565-6222

Tower Infectious Diseases
Jennifer Ida, PharmD
(310) 358-2300 ext. 228

93. KS Treatment: LGD1069 (Targretin)

Title:

L1069-21: A Phase II Evaluation of Targretin Capsules in Patients with AIDS-Related Kaposi's Sarcoma

Type of treatment:

LGD 1069 (Targretin): anti-KS

Purpose:

To see if LGD1069 (also called Targretin) is safe and well tolerated and to see if it is effective in treating KS lesions in AIDS patients.

About the study:

All patients will receive Targretin. There are no placebos in this study. Targretin is a capsule taken by mouth once a day. The dose of Targretin may be lowered depending on any toxic side effects patients may experience. Study visits are every two weeks and the study lasts for 16 weeks. If the study remains open and active, patients may continue treatment for as long as the treatment is considered to be of clinical benefit and has not shown severe side effects.

Required:

- CD4 cell (T-cell) range: not specified
- Viral load range: not specified
- HIV positive
- At least 18 years old
- Diagnosis of KS proven by biopsy. Patients must have a minimum of six lesions, three of which are raised, and have been present for at least 30 days or measure at least 1.0 cm.
- Must have been on stable antiretroviral therapy for at least six weeks prior, during, and at least one month after drug discontinuation

Not allowed:

- Women who are pregnant or breastfeeding
- Systemic treatment for KS within 30 days of study entry
- Systemic treatment with Vitamin A (more than 15,000 IU per day) or other retinoid class drugs within 30 days of study entry
- Previous treatment of study lesions with any local or topical therapy within 60 days of study entry

- Concurrent serious, uncontrolled infections such as MAC, PCP, CMV, toxoplasmosis or meningitis
- Any known allergy to retinoid class drugs
- Concurrent treatment with local or topical therapy such as Vitamin A, cryotherapy, radiation therapy, intralesional injection or photodynamic therapy for any study lesion

Location:

AIDS Healthcare Foundation
Edwin Graham, RN
(213) 668-4843

Desert Hospital Comprehensive Cancer Center
Terry Bryntesen, RN
(619) 416-4734

94. KS Treatment: IM-862

Title:

17K-96-3: IM-862 Product Nasal Solution Open Label Investigator Protocol for Evaluation of IM-862 Treatment in Kaposi's Sarcoma Subjects

Type of treatment:

IM-862:

Purpose:

To see if the new drug IM-862 is safe and effective in treating KS lesions

About the study:

Patients are assigned by chance to receive one of two treatment schedules using IM-862. IM-862 is a nasal solution and applied to the nose much like nose drops. One group will take IM-862 every other day for 90 days. The other group will take IM-862 for five consecutive days followed by five days of rest.They will repeat this cycle for 90 days. All patients will be taking IM-862. There are no placebos. Study visits are every two weeks and the study lasts 90 days.

Patients will have two skin biopsies on a KS lesion during the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven diagnosis of KS of the skin with at least five lesions involving the skin or oral cavity

Not allowed:

- Any AIDS-defining opportunistic infections
- Use of steroids within 14 days of study entry
- Use of interferons, interleukins or chemotherapy within three weeks of study entry
- Radiation therapy within four weeks of study entry
- Previous use of IM-862
- Women who are pregnant or breastfeeding
- Past or current other cancer excluding basal cell skin cancer or cervical cancer
- Active drug or alcohol abuse

Location:

LAC-USC Medical Center
Suzanne Cabriales, RN
(213) 343-8270

95. KS Treatment: Radiation

Title:

UCD95KS001: A Prospective, Randomized Controlled Trial of Radiation Therapy for Early Stage AIDS-Associated Kaposi's Sarcoma

Type of treatment:

Radiation

Purpose:

To see which dose of radiation is best for treating localized KS lesions.

About the study:

Patients entering this study must have at least two KS lesions that could benefit from therapy. Two lesions will be treated with different doses of radiation. One lesion will receive a lower dose once. The other lesion will receive a higher dose every day for ten days. Patients will come to the clinic everyday for two weeks during radiation treatment. Follow-up visits are at one month, then every two months until progression of the treated lesions. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- At least two, biopsy-proven KS lesions of the skin

Not allowed:

- Any other cancers in the past five years, except non-melanoma skin cancer
- KS of the internal organs

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

New

96. KS Treatment: TNF Receptors

Title:

Phase II Study of Soluble TNF Receptors in Patients with AIDS and Kaposi's Sarcoma

Type of treatment:

TNF Receptors: immune modulator

Purpose:

To see if soluble TNF receptors are safe and to see what effect they have on tumor growth.

About the study:

All patients in this study will receive soluble TNF receptors. TNF is given by injection under the skin. Patients will receive injections twice a week for 12 weeks. Because immunme modulators such as TNF can activate HIV, all patients must take some form of antiretroviral therapy.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 12 years old
- Biopsy-proven KS
- Must be taking some form of antiretroviral therapy

Not allowed:

- Greater than 50 KS lesions on the skin and/or KS of the internal organs
- Any other cancers except cervical or basal cell
- Women who are pregnant or breastfeeding
- Patients with more than 200 T-cells must never have had an opportunistic infection; patients with less than 200 T-cells may not have an uncontrolled concurrent opportunistic infection
- Prior cardiac disease
- Use of immunomodulators, interferons, Megace or Trentol within four weeks of study entry

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

97. CNS Non-Hodgkin's Lymphoma: Chemotherapy, Radiation

Title:

ACTG 252: Phase II Trial of Sequential Chemotherapy and Radiotherapy for AIDS-Related Primary Central Nervous System Lymphoma and Laboratory Correlate: Epstein-Barr Virus in Cerebrospinal Fluid in AIDS-Related Primary Central Nervous System Lymphoma

Type of treatment:

Chemotherapy, systemic
Radiation

Purpose:

To find out if treating patients with chemotherapy (drugs to fight cancer), followed by radiation therapy is an effective treatment for primary Central Nervous System lymphoma.

About the study:

Before starting treatment, samples of the cerebrospinal fluid (CSF) and bone marrow will be taken. A tube is inserted between the bones of the spine in the lower back to collect a sample of CSF. Bone marrow is collected by inserting a needle into the hip bone. On the first day, patients will be given chemotherapy (cyclophosphamide, doxorubicin, vincristine and dexamethasone). These drugs are injected into a vein. After the first day, patients will take dexamethasone by mouth every day. Patients will also take G-CSF for 10 days. G-CSF is given by injection just under the skin. Patients will be taught how to give themselves injections at home. After patients stop chemotherapy, they will receive radiation therapy to the brain. Radiation therapy will be given 5 days a week for 4 weeks. Patients will come to the clinic once a week to have blood drawn. The study lasts about one month.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- 16 years or older
- CNS non-Hodgkin's lymphoma

Not allowed:

- Ever had chemotherapy (except for Kaposi's sarcoma)
- Ever had radiation therapy of the brain
- Pregnant or breastfeeding women
- Current treatment with an investigational drug (except antiretroviral drugs available through a treatment IND)

Location:

UCSF AIDS Program at SFGH/ACTU
Carol Arri, RN
(415) 476-9296 ext. 351

98. Non-Hodgkin's Lymphoma Treatment: Gallium Nitrate

Title:

A Phase II Evaluation of Gallium Nitrate (NSC 15200) in Non-Hodgkin's Lymphoma Associated with AIDS

Type of treatment:

Gallium Nitrate: anti-cancer

Purpose:

To see how quickly and how long patients respond to treatment with gallium nitrate after they have failed treatment with chemotherapy drugs. To see what side effects gallium nitrate may cause.

About the study:

All patients will receive gallium nitrate. Gallium nitrate is given by injection into a vein (infusion). Infusions are given every day for seven days and repeated every three weeks. Patients who experience complete remission will receive two additional treatments. If patients relapse, they may restart the treatment program. The study will last indefinitely.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Diagnosis of non-Hodgkin's lymphoma
- Patients must have failed one potentially curative treatment for lymphoma
- A lumbar puncture (spinal tap) will be performed at the beginning of the study

Not allowed:

- CNS lymphoma
- Any other cancer except cervical, basal cell of the skin or KS of the skin and not requiring chemotherapy
- Any severe, acute opportunistic infection
- Current radiation therapy or other chemotherapy
- Women who are pregnant or breastfeeding
- Significant cardiovascular disease, such as recent heart attack, past congestive heart failure, angina, or serious arrythmias

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

99. AIDS-Related Lymphoma Treatment: Chemotherapy

Title:

A Phase II, Open-Label Study of Infusional Chemotherapy in the Treatment of AIDS-Related Lymphoma

Type of treatment:

Chemotherapy, systemic

Purpose:

To see how long it takes for lymphoma to respond to the treatment and how long the response lasts; to see how safe this treatment is and what side effects it has.

About the study:

All patients will receive a combination of cyclophosphamide, mitoxantrone and etoposide. These drugs are given as an infusion into a vein. Patients will need to have a central line. A central line is a tube inserted into a vein in the chest area and involves minor surgery. Infusions will take place every three to four weeks. Patients will be in this study for four to six months.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 17 years old
- A diagnosis of B-cell immunoblastic lymphoma, small non-cleaved (either Burkitt or Burkitt-like) lymphoma, large non-cleaved or large-cleaved lymphoma

Not allowed:

- Any acute infection within two weeks of starting the study
- Any other cancer, other than KS or cervical cancer not requiring chemotherapy
- Primary CNS lymphoma
- Use of AZT during the study
- Past use of cytotoxic chemotherapy
- Any radiation therapy with four weeks of study entry
- Any immunomodulators within two weeks of study entry
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

100. Non-Hodgkin's Lymphoma Treatment: Mitoguazone (MGBG), CHOP Chemotherapy

Title:

A Phase II Study of Mitoguazone In Combination with CHOP Chemotherapy in Patients with Newly Diagnosed AIDS-Related Non-Hodgkin's Lymphoma

Type of treatment:

Chemotherapy, systemic: chemotherapy
Mitoguazone dihydrochloride: chemotherapy

Purpose:

To see if mitoguazone (MGBG) combined with CHOP chemotherapy (cyclophosphamide, adriamycin, vincristine, prednisone) is a safe and effective treatment for non-Hodgkin's lymphoma.

About the study:

All patients will receive mitoguazone and CHOP chemotherapy. CHOP chemotherapy consists of cyclophosphamide, adriamycin and vincristine given by infusion into a vein. Prednisone will be given orally on days 1-5. Mitoguazone will be given on days 1 and 15. CHOP chemotherapy will be given on day 1. This cycle is repeated every 28 days. Study visits are every

two weeks and the study lasts four to six months. Patients will be evaluated by CAT scans, MRI or CT of the head, and a lumbar puncture (spinal tap) at the beginning of the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 18 years old
- Newly diagnosed non-Hodgkin's lymphoma, not previously treated

Not allowed:

- Acute infections
- Other cancers except skin, cervical or KS that does not require systemic therapy
- CNS lymphoma
- Past use of cytotoxic chemotherapy
- Any radiation therapy within four weeks of study entry
- Any immunomodulators (interferons, interleukins) within two weeks of study entry
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

101. CNS Lymphoma Treatment: MGBG Chemotherapy, Radiation

Title:

A Phase II, Open-Label Study of MGBG Chemotherapy with Radiotherapy for AIDS-Related Primary CNS Lymphoma

Type of treatment:

MGBG: chemotherapy
Radiation

Purpose:

To see if MGBG chemotherapy combined with radiation therapy is safe and effective in treating primary CNS lymphoma.

About the study:

All patients will receive MGBG chemotherapy and radiation. MGBG is given by infusion into a vein. Chemotherapy is given on day 1, day 8, and then every two weeks. Radiation to the brain is also given beginning at week four and given over a period of approximately four to five weeks. The study will last one year. Patients will get a CAT scan or MRI scan of the brain, bone marrow biopsy, chest X-ray and a CAT scan of the chest, pelvis and abdomen at the beginning of the study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Between 18 and 70 years old
- Newly diagnosed CNS lymphoma

Not allowed:

- Current serious infections
- Lymphoma outside the nervous system
- Other cancers excluding skin cancer or KS
- Significant cardiovascular disease including recent heart attack or past congestive heart failure, chest pains or serious cardiac arrhythmias
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

102. Non-Hodgkin's Lymphoma Treatment: PEG L-Asparaginase

Title:

17NHL-96-3: A Phase I Study of PEG L-asparaginase in the Treatment of Refractory/Relapsed AIDS-Related Non-Hodgkin's Lymphoma (AIDS-NHL)

Type of treatment:

L-Asparaginase: anticancer

Purpose:

To see if PEG L-Asparaginase is safe and to determine the maximum dose that is tolerated in patients who have relapsed NHL or are not responding to other treatment. To see how PEG L-asparaginase is processed by the body. To see what level of anti-tumor response PEG L-asparaginase has.

About the study:

This is a dose-ranging or dose-escalating study. This means that the first patients to enroll on the study will receive the lowest dose of PEG L-asparaginase. If this dose is found to be well-tolerated, the next group of patients will receive a higher dose. This procedure is followed until the highest dose of PEG L-asparaginase that researchers plan to study has been given OR the highest dose is found which does not cause bad side effects. PEG L-asparaginase is given by injection into a muscle. Patients will receive injections every two weeks until they develop intolerable side effects OR they have complete remission (disappearance of lymphoma) OR they choose to stop the treatment. Study visits are every two weeks and the study lasts at least one month. Patients will be required to have a lumbar puncture (spinal tap), CT scan of the head and bone marrow biopsy at the beginning of the study.

Required:

- CD4 cell (T-cell) range: not applcable
- Viral load range: not applicable
- HIV positive
- At least 17 years old
- Diagnosis of non-Hodgkin's lymphoma that has come back OR never gone away with prior exposure to any chemotherapy or radiation treatment

Not allowed:

- Acute intercurrent infection
- Patients with other cancers except basal cell carcinoma, cervical cancer, or KS of the skin, not requiring systemic chemotherapy
- CNS lymphoma
- Past or current pancreatitis
- Treatment with chemotherapy or radiation therapy within two weeks of study entry
- Prior use of L-asparaginase
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Laura Harvey-Buchanan, RN
(213) 226-4578

103. Non-Hodgkin's Lymphoma Treatment: DaunoXome

Title:

103-41: DaunoXome In the Treatment of HIV-Associated Refractory or Relapsed Non-Hodgkin's Lymphoma (Phase II)

Type of treatment:

DaunoXome: chemotherapy

Purpose:

To see if DaunoXome is safe and effective in treating non-Hodgkin's lymphoma in patients that have tried at least one other treatment with no response and/or for patients who have relapsed after treatment.

About the study:

All patients enrolling in this study will have tried at least one other potential treatment or have relapsed after using that treatment. All patients will receive DaunoXome. DaunoXome is given by infusion into a vein. Medication is given every three weeks. This study will last indefinitely. Patients are required to have a bone marrow biopsy for this study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Confirmed diagnosis of intermediate or high grade non-Hodgkin's lymphoma
- Patients must have received at least one potential treatment for non-Hodgkin's lymphoma

Not allowed:

- Any chemotherapy, radiation or hormone therapy must have been discontinued for at least two weeks prior to enrollment
- Patients with CNS lymphoma
- Women who are pregnant or breastfeeding
- Any active AIDS-defining opportunistic infection within two weeks prior to enrollment, except herpes simplex or oropharangeal candidiasis (thrush)
- Cardiac conditions such as atrial arrhythmias, unstable angina, or myocardial infarction, congestive heart failure, coronary artery bypass or coronary angiopasty
- Any cancers other than skin, cervical, or KS of the skin

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Byron Espina
(213) 764-0371

104. Epstein Barr-Associated Malignancies Treatment: 5-Azacytidine

Title:

T93-0116: A Pilot Study of 5-Azacytidine Given as a 7-Day Continuous Infusion in HIV Patients with Relapsed and/or Refractory EBV-Associated Malignancies

Type of treatment:

5-Azacytidine: anticancer

Purpose:

To see if 5-azacytidine is a safe and effective treatment for patients with Epstein Barr-associated malignancies that have not gotten better with standard chemotherapy treatment.

About the study:

Patients will enter the hospital and receive 5-azacytidine for seven consecutive days. 5-azacytidine is given by infusion into a vein. All patients will receive 5-azacytidine. There are no placebos. Patients will receive one to three courses of treatment (infusion over one week every 28 days) depending on how well the treatment is tolerated and on how the tumor responds to treatment. The study lasts at least two months.

Required:

- CD4 cell (T-cell) range: not applicable
- At least 18 years old
- HIV positive
- Diagnosis of Hodgkin's or non-Hodgkin's lymphoma with Epstein Barr virus involvement

Not allowed:

- CNS cancers
- Women who are pregnant or breastfeeding
- Active, uncontrolled infections

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Joanne Shifflett, RN
(213) 226-4578

New

105. AIDS-Associated Lymphoma Treatment: 90Y-Lym-I

Title:

UCD-RT0301: Immunotherapy of AIDS-Associated Lymphoma With 90Y-Lym-1

Type of treatment:

90Y-Lym-1: anticancer

Purpose:

To see if 90Y-Lym-1 is a safe and effective treatment for AIDS-associated lymphoma.

About the study:

All patients in this study will receive 90Y-Lym-1. 90Y-Lym-1 is given by infusion into a vein. Infusions are given every four weeks for 12 weeks. Patients will be in this study until their lymphoma progresses.

Required:

- CD4 cell (T-cell) range: at least 25
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Diagnosed with AIDS-associated lymphoma

Not allowed:

- Any other cancers within the last five years, except non-melanoma skin cancer and KS of the skin
- Women who are pregnant or breastfeeding

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

New

106. Non-Hodgkin's Lymphoma Treatment: IL-2

Title:

AMC-003: Low-Dose Interleukin-2 in AIDS-Lymphoma: A CALGB Study

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To see what effect interleukin-2 (IL-2) has on tumor response and survival and to see if it has any activity against HIV infection.

About the study:

Interleukin-2 is given by injection under the skin. Patients will be taught how to give themselves injections at home. Injections will be given every day for one year. Patients will need to come to the clinic every two weeks to pick up a supply of syringes already filled with IL-2. Study visits are at weeks 6, 10, 12, then every 12 weeks for one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 16 years old
- Diagnosis of non-Hodgkin's lymphoma that is in partial remission after completing standard therapy

Not allowed:

- Women who are pregnant or breastfeeding
- Current opportunistic infections
- Any other cancers other than basal cell of the skin
- CNS lymphoma
- Previous treatment with IL-2

Location:

LAC-USC Medical Center - Norris Cancer Hospital
Byron Espina
(213) 764-0371

107. MAC Treatment: Clarithromycin, Ethambutol, Azithromycin

Title:

066-189/189B: A Randomized, Double Blind, Comparative Study of Azithromycin vs. Clarithromycin in combination with Ethambutol for the Treatment of Disseminated *Mycobacterium avium* Complex (MAC) Infection in AIDS Patients

Type of treatment:

Azithromycin: antibacterial
Clarithromycin: antibacterial
Ethambutol: antimycobacterial

Purpose:

To compare the safety and effectiveness of two different doses of azithromycin and clarithromycin in combination with ethambutol for treatment of MAC.

About the study:

All patients in this study take ethambutol pills. In addition, patients are assigned by chance to take either azithromycin pills or clarithromycin pills. Neither patients nor their doctors know who is taking azithromycin and who is taking clarithromycin until the study ends. The study lasts six months.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 13 years old
- Disseminated MAC infection, proven by a blood culture. (Disseminated means that the infection has spread throughout the body)

- No treatment for MAC since the last positive blood culture.
- Patients who are taking one (and only one) drug to prevent MAC are eligible.

Not allowed:

- Pregnant or nursing women
- Taking any other experimental drug within one week before starting this study

Location:

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

108. MAC Treatment: Clarithromycin, Rifabutin, Ethambutol

Title:

ACTG 223: A Phase II/III Prospective, Multicenter, Randomized, Controlled Trial Comparing the Safety and Efficacy of Three Clarithromycin-Containing Combination Drug Regimens for the Treatment of Disseminated *Mycobacterium avium* Complex (MAC) Disease in Persons with AIDS

Type of treatment:

Clarithromycin: antibacterial
Ethambutol: antimycobacterial
Rifabutin: antimycobacterial

Purpose:

To find out if clarithromycin is safe and helpful for treatment of MAC infection when used in combination with rifabutin and/or ethambutol.

About the study:

Everyone in the study takes clarithromycin. In addition, patients ar assigned by chance to receive rifabutin, ethambutol, or a combination of rifabutin and ethambutol. All patients will know which treatment thay are taking. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- MAC disease with symptoms and a positive blood culture
- Between 18 and 65 years old

Not allowed:

- Current treatment with Seldane or Hismanol
- Current treatment for active infection requiring fluconazole for more than 21 days
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center
Frances Canchola, RN
(213) 343-8281

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

UCSF AIDS Program at SFGH/ACTU
Carol Arri, RN
(415) 476-9296 ext. 351

109. MAC Treatment: Clarithromycin, Ethambutol, Filgrastim (G-CSF)

Title:

G-CSF-940236: A Prospective, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group, Phase II Study Comparing the Safety and Efficacy of Clarithromycin and Ethambutol Plus Placebo versus Clarithromycin and Ethambutol Plus Filgrastim (G-CSF) in the Treatment of Disseminated *Mycobacterium avium* Complex Infection (MAC) in HIV-Infected Patients

Type of treatment:

Clarithromycin: antibacterial
Ethambutol: antimycobacterial
G-CSF: white blood cell stimulator

Purpose:

To see if Filgrastim (G-CSF), when used with clarithromycin and ethambutol, decreases the time to clear Mycobacterium avium from the blood compared to using clarithromycin and ethambutol alone.

About the study:

All patients will take clarithromycin and ethambutol. Patients are assigned by chance to receive Filgrastim or placebo. Neither patients nor their doctors will know if they are getting Filgrastim or not until the study ends. Clarithromycin and ethambutol are pills and taken by mouth. Filgrastim and its placebo are given by injection under the skin once a day. Patients will have two bone marrow evaluations; one at the beginning of the study and one at week 2, week 4 or week 8, depending on their assignment. Study visits are once a week for eight weeks, then once a month for one year. Patients will be paid $150 for each bone marrow biopsy.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- At least 13 years old
- Diagnosis of disseminated MAC

Not allowed:

- Any cancer requiring systemic chemotherapy within 12 weeks of study entry
- Patients who have failed clarithromycin for MAC prevention
- Chest X-ray showing active infection or tuberculosis
- Currently using IV ganciclovir for a new CMV infection (induction); maintenance ganciclovir is okay

- Women who are pregnant or breastfeeding
- Use of any immunomodulators within 14 days of study entry

Location:

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

Shared Medical Research Foundation
Vicky Ramirez
(818) 345-2172

New

110. MAC Treatment: VIRACEPT (nelfinavir), Standard Treatment

Title:

AG1343-518: A Pilot, Phase II, Randomized, Placebo-Controlled Study to Determine the Effects of VIRACEPT on the Clinical Outcome of Disseminated *Mycobacterium avium* Complex Disease (MAC) in AIDS Patients who are Receiving Standard Acute Treatment for this Opportunistic Infection

Type of treatment:

Azithromycin: antibacterial
Ethambutol: antimycobacterial
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see if VIRACEPT is safe and effective for people who are undergoing acute treatment for disseminated MAC infection.

About the study:

All patients will receive standard treatment for MAC (azithromycin and ethambutol). Patients are assigned by chance to receive VIRACEPT or placebo to add to their MAC treatment medications for three months. After three months, all patients will receive open-label (real) VIRACEPT and be followed for an additional nine months. Study visits are every two weeks for the first month, then once a month till the end of the study. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Patients must be newly diagnosed with MAC and have less than seven days of MAC therapy

Not allowed:

- Women who are pregnant or breastfeeding
- Patients with cancers requiring chemotherapy or radiation or have used such therapies within one month of study entry
- Prior use (more than 14 days) of a protease inhibitor other than saquinavir (Invirase)
- Active substance abuse
- Significant malabsorption syndrome

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

111. PCP Prevention: Atovaquone, Aerosolized Pentamidine

Title:

A Randomized, Open Label Trial of High Dose Atovaquone versus Low Dose Atovaquone versus Aerosolized Pentamidine for Prophylaxis of *Pneumocystis carinii* Pneumonia in Patients with HIV Infection Who are Intolerant of TMP/SMX

Type of treatment:

Atovaquone: antibacterial
Pentamidine, aerosolized: antiparasitic (PCP)

Purpose:

To find out if high dose atovaquone in liquid form is effective in preventing AIDS pneumonia (*Pneumocystis carinii* Pneumonia, or PCP) in patients who cannot take trimethoprim/sulfamethoxazole (also called Septra or Bactrim) and who have had one or more episodes of PCP. To learn about the safety of liquid high dose atovaquone.

About the study:

Patients are assigned by chance to high or low dose atovaquone or aerosolized pentamidine. Atovaquone is taken in liquid form once a day. Aerosolized pentamidine is inhaled into the lungs as a very fine mist, using a device called a nebulizer. It is given once a month. Each treatment takes about 30 minutes. The study lasts 16 months.

Required:

- CD4 cell (T-cell) range: below 200 or, have had PCP before
- HIV positive
- Cannot take Septra or Bactrim because of side effects
- At least 13 years old

Not allowed:

- Taking any other drug which acts against PCP
- Active PCP. If a patient has active PCP, it must be treated before s/he can start the study

Location:

East Bay AIDS Center
Nancy Orcutt, RN, MS
(510) 204-1291

HIVCare, Saint Francis Memorial Hospital
Sher Vieira
(415) 353-6215

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

112. PCP Prevention: TMP/SMX Desensitization

Title:

CBCTN 06: Trimethoprim Sulfamethoxazole (TMP/SMX) Desensitization Versus Direct Rechallenge in HIV-Infected Patients Who Are at High Risk for PCP and Have Experienced Adverse Reactions to TMP/SMX

Type of treatment:

TMP/SMX Desensitization: antibacterial

Purpose:

To compare patients who gradually increase their dose of TMP/SMX (also called Bactrim or Septra) every day for six days to a full single-strength dose by day six to those who start taking the full single-strength dose. To compare the time from starting the medication to the time patients experience a reaction to TMP/SMX, the frequency of using other drugs to reduce the reaction, or are diagnosed with PCP.

About the study:

Patients will be assigned by chance to receive either a TMP/SMX liquid or a TMP/SMX tablet. Those patients assigned to a liquid will drink a higher dose each day for six days and they will also take a placebo pill. The other group will receive a TMP/SMX single strength tablet which is taken every day and will receive a placebo liquid to swallow for six days. Neither patients nor their doctors will know which they are taking for six days. After six days, all patients will be taking real single-strength TMP/SMX pills for six months. There are two study visits; day one and at six months. Additional visits, if required, may be done in person or by phone. The study lasts 6 months.

Required:

- CD4 count (T-cell) range: not specified
- HIV positive
- At least 13 years old
- Have had to stop taking TMP/SMX in the past because of fevers or rash
- Patients must require PCP prophylaxis

Not allowed:

- History of severe adverse reactions to TMP/SMX, such as anaphylaxis, Stevens-Johnson syndrome, mucosal lesions, bronchospasm

Location:

HIVCare, Saint Francis Memorial Hospital
Sher Vieira
(415) 353-6215

113. Peripheral Neuropathy Treatment: Acupuncture

Title:

CPCRA 022: The Efficacy of a Standardized Acupuncture Regimen and Amitriptyline Compared with Placebo as a Treatment For Pain Caused by Peripheral Neuropathy in HIV-Infected Patients

Type of treatment:

Acupuncture: Chinese medicine
Amitriptyline: antidepre

CLOSED

Purpose:

To find out hov acupuncture treatments, v hout amitriptyline (Ela r pain in the legs and fe by peripheral neuropathy.

About the study:

Patients are assigned by chance to receive either acupuncture treatments or "alternate points" acupuncture. "Alternate points" acupuncture involves placing the acupuncture needles in points that are not harmful, but have not been proven to be helpful. Patients are also assigned by chance to receive amitriptyline (Elavil) or placebo. Both amitriptyline and its placebo are pills and taken by mouth. Patients do not know which treatment is being given until the study ends. Patients must keep a daily pain diary while in the study. The study lasts 14 weeks. People who complete the study will be given ten free acupuncture treatments.

Required:

- CD4 cell (T-cell) rang cified
- Painful peripheral caused by HIV
- At least 13

CLOSED

Not allow

- Active nistic infection
- Currently aking anti-depressant drugs, and unwilling to stop for the study.

Location:

Community Consortium
To be arranged through physician-see page 103
(415) 476-9554

114. HIV Sensory Neuropathy Treatment: rhNGF

Title:

ACTG 291: A Phase II, Double-Blind Trial of Recombinant Human Nerve Growth Factor for Treatment of HIV-Associated Sensory Neuropathy

Type of treatment:

Nerve Growth Factor:

Purpose:

To see if nerve growth factor is a safe, effective and well-tolerated way to treat peripheral neuropathy.

About the study:

Patients are assigned by chance to receive nerve growth factor or a placebo. Both nerve growth factor and its placebo are given by injection under

the skin. Neither patients nor their doctors will know which they are receiving until the study ends. Injections will be given twice a week. Study visits are every two weeks and the study lasts 22 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Between 18 and 70 years old
- Diagnosis of peripheral neuropathy made by a neurologist. A neurology exam will be included in the screening process
- Unchanged (stable) antiretroviral therapy or NO antiretroviral therapy for at least 8 weeks prior to starting the study

Not allowed:

- Acute, active opportunistic infections (except oral thrush, oral or genital herpes, or MAI infection in the blood) within two weeks prior to study entry
- Peripheral neuropathy due to any cause other than HIV
- Any major, active psychiatric disorder
- Active cancer requiring treatment (except KS of the skin)
- Systemic chemotherapy within 90 days; some chemotherapy may be allowed within 30 days of study entry - call to find out
- Systemic corticosteroids or immunomodulators (thalidomide, interferons, interleukins) within 30 days prior to study entry
- Treatment for acute opportunistic infection within 14 days of study entry (maintenance treatment of CMV retinitis, MAI bacteremia, or cryptococcal meningitis is permitted)
- Women who are pregnant or breastfeeding
- Any active alcohol or drug abuse

Location:

AIDS Community Research Consortium
Sharon O'Leary, RN
(415) 364-6563

Stanford University Medical Center
Jane Norris, PA
(415) 723-6231

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF AIDS Clinic
Sue Forstat, LVN
(415) 476-3226

UCSF AIDS Program at SFGH / ACTU
David Gary, RN
(415) 476-9296, ext. 354

115. Prurigo Nodularis: Thalidomide

Title:

Thalidomide for the Treatment of Refractory Prurigo Nodularis and Photodermatitis in Patients With HIV Infection

Type of treatment:

Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To see if thalidomide is safe and effective as a treatment for itchy bumps on the skin associated with HIV infection. These bumps must be diagnosed as "Prurigo Nodularis" and not have responded to any other treatment.

About the study:

Patients are assigned by chance to receive one of two doses of thalidomide. All patients will take real thalidomide. A skin biopsy is required at the beginning and at the end of the study. A skin biopsy is the removal of a small piece of skin. The study lasts one year and study visits are every month. Blood will be drawn every three months.

Required:

- CD4 (T-cell) range: not specified
- HIV positive
- Prurigo nodularis (itchy skin bumps proven by biopsy) that have not gone away with steroid treatment
- 18 years of age or older

Not allowed:

- Pregnant or nursing women
- Moderate-severe peripheral neuropathy
- Currently taking ddC, d4T or systemic chemotherapy

Location:

SFGH Dermatology
Toby Maurer, MD
(415) 206-8680

116. Sinusitis Treatment: Acupuncture, Herbs, Augmentin

Title:

FDA 243A: Acupuncture and Herbal Treatment of Chronic HIV Sinusitis

Type of treatment:

Acupuncture: Chinese medicine
Augmentin: antibacterial
Chinese Herbs: Chinese Medicine

Purpose:

To find out if traditional Chinese medicine or an antibiotic medicine (Augmentin) is better at reducing symptoms of sinusitis, and at preventing sinusitis from coming back.

About the study:

Patients will be assigned by chance to receive acupuncture and Chinese herbs or Augmentin. The study lasts 12 weeks with 8 weeks of treatment and 4 weeks of no treatment. Study visits will be weekly. Patients will be required to have an examination of their nasal cavity as well as a CAT scan of their nasal

passages. These exams will be repeated 30 days after the study ends. Use of any antibiotics other than Septra/Bactrim or use of acupuncture/Chinese herbs not prescribed as part of the study is not allowed during the study.

Required:

- CD4 cell (T-cell) range: at least 50
- HIV positive
- History of recurrent sinusitis

Not allowed:

- Active infection with fever over 102
- Any active opportunistic infection
- Pregnant oe nursing women

Location:

Immune Enhancement Project
Thomas Sinclair, LAc
(415) 252-8711

117. TB Prevention: Isoniazid, Rifabutin

Title:

A Phase III Controlled, Double-Blind, Randomized, Multinational Study for the Preventive Therapy of Latent Tuberculosis in HIV-Positive Individuals: Isoniazid (300 mg/d x 12 mos) versus Rifabutin (300 mg/d x 3 mos)

Type of treatment:

Isoniazid: antimycobacterial
Rifabutin: antimycobacterial

Purpose:

To compare rifabutin and isoniazid to see which is more effective in preventing people with both HIV infection and TB infection from getting active tuberculosis.

About the study:

Patients are assigned by chance to receive either isoniazid daily for one year or rifabutin daily for three months. All patients will take pills (real and placebo) for one year. Neither patients nor their doctors will know which they are receiving. Study visits are once a month for one year.

Required:

- CD4 cell (T-cell) range: unspecified
- HIV positive
- At least 18 years old
- Positive PPD skin test (mantoux method)

Not allowed:

- More than 2 months of any anti-TB drugs after a positive PPD test
- Prior active TB
- Acute hepatitis
- Peripheral neuropathy
- Women who are pregnant or nursing

Location:

San Francisco VA Medical Center
Bill Stanton, RN
(415) 221-4810, ext. 4798

118. TB Treatment: Rifapentine, Isoniazid, Rifampin

Title:

Efficacy and Safety of Once-Weekly Rifapentine and Isoniazid Compared to Twice-Weekly Rifampin and Isoniazid in the Continuation Phase of Therapy for Pulmonary Tuberculosis

Type of treatment:

Isoniazid: antimycobacterial
Rifampin: antimycobacterial
Rifapentine: antifungal

Purpose:

To compare two different treatment strategies for people with tuberculosis to learn which is easier to follow and more effective in preventing multi-drug resistant tuberculosis.

About the study:

Patients are assigned by chance to receive rifapentine and isoniazid pills once a week or rifampin and isoniazid pills twice a week for six months. Both treatments must be taken in the presence of a study employee, either at the clinic or at patients' homes, this is called "Directly Observed Therapy". The study requires monthly clinic visits for the first four months, then every three months for a year, and then two times in the last year for a total of 2 ½ years on study. Participants are compensated $20 a week for the first six months and then $10 per visit for the last two years.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive or negative
- Diagnosed with pulmonary TB
- Documented directly observed therapy with a 4-drug combination for 8 weeks
- Fully susceptible to INH and Rifampin
- At least 18 years old

Not allowed:

- Have received more than 70 days of treatment for tuberculosis at study entry
- Pregnant or breastfeeding women
- Other conditions requiring treatment with anti-TB drugs

Location:

LAC-USC Medical Center
Claudia Silva, RN
(213) 343-8268

San Francisco VA Medical Center
Bill Stanton, RN
(415) 221-4810, ext. 4798

119. TB Treatment: Rifampin, INH, Ethambutol, Pyrazinamide

Title:

ACTG 309: Pharmacokinetics of Antituberculosis Agents in HIV-Infected Persons with Tuberculosis

Type of treatment:

Ethambutol: antimycobacterial
Isoniazid: antimycobacterial
Pyrizinamide: antimycobacterial
Rifampin: antimycobacterial

Purpose:

To see how rifampin, INH, ethambutol and pyrazinamide are processed by the body in HIV-infected persons and to compare this to the way these drugs are processed in non-HIV-infected persons.

About the study:

Patients will take at least two and up to all four of the study drugs based on their doctor's decision. The study will cover the cost of the medications for eight weeks. Patients will know what medications they are taking. There are two study visits; one at week two and again at week six. These study visits are approximately 10 hours long and involve blood collection. Patients will be paid $25 for each 10 hour outpatient visit.

Required:

- CD4 cell (T-cell) range: unspecified
- Viral load range: unspecified
- Positive acid fast smear with TB cultures pending

Not allowed:

- Use of TB medications for more than one week prior to study entry

Location:

Harbor-UCLA Medical Center
Sally Kruger
(310) 222-3848

120. HIV Wasting Treatment: Nandrolone Decanoate

Title:

A Randomized, Double-Blind, Placebo-Controlled Study of Nandrolone Decanoate for HIV-Associated Wasting

Type of treatment:

Nandrolone Decanoate: steroid

Purpose:

To see if nandrolone decanoate is a safe and effective treatment for weight loss in people with HIV.

About the study:

Patients are assigned by chance to receive an injection of nandrolone decanoate or a placebo injection every week for 12 weeks. Neither patients nor their doctors will know which they are receiving until the study ends. After 12 weeks, all study patients will receive open-label nandrolone decanoate for an additional 12 weeks. Study visits will take place weekly and the study will last 24 weeks. Patients will be paid $500 for completing this study.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Unintended loss of more than 10% of usual body weight
- Normal blood testosterone level
- At least 18 years old

Not allowed:

- Active opportunistic infection
- Use of other steroids, appetite-stimulating drugs or other drugs intended to treat weight loss, including growth hormone, megace, marinol, thalidomide, etc.
- Diarrhea, defined as more than five liquid stools per day
- Treatment for cancer other than KS
- Women who are pregnant or nursing

Location:

UCSF/SFGH Endocrinology
Heather Algren
(415) 206-3319

121. HIV Wasting Treatment: Testosterone, Exercise

Title:

A Pilot, Randomized Study of Testosterone/Exercise for HIV Wasting

Type of treatment:

Exercise: exercise
Testosterone: steroid

Purpose:

To see if testosterone alone or in combination with exercise is an effective treatment for HIV wasting.

About the study:

Patients are assigned by chance to receive injections of testosterone or placebo. Patients are also assigned by chance to participate in an exercise program at a specified gym or maintain their current activity level. Patients will know if they are assigned to exercise or maintain current activity but will not know if they are receiving testosterone or placebo until the study ends. The study requires two overnight stays at the hospital for body composition tests. Frequency of study visits will vary for each participant and the study lasts six months. Patients will be paid for their participation.

Required:

- CD4 cell (T-cell) range: not specified
- Men only
- HIV positive
- Blood testosterone level below normal
- Loss of 10% or more of usual body weight

Not allowed:

- Female patients

Location:

Harbor-UCLA Medical Center
Brenda
(310) 222-1859

122. HIV Wasting Treatment: Testosterone

Title:

Testosterone Patches versus Testosterone Enanthate in AIDS Patients with Wasting

Type of treatment:

Testosterone: steroid

Purpose:

To see if testosterone patches or testosterone injections supply more drug to the body and to see if testosterone has any effect on thyroid metabolism.

About the study:

Patients will be assigned by chance to receive either testosterone injections every two weeks or to receive a testosterone patch. Patients assigned to a patch will wear a fresh patch every day for about 22 hours. Patches are worn on the scrotum. Study visits are every two weeks and study treatment will last 16 weeks.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Male
- Diagnosis of wasting syndrome

Not allowed:

- Current treatment with other hormones, megace, pentoxifylline, thalidomide, vasnarinone, chloropromazine, or warfarin
- Female patients
- Substance abuse

Location:

LAC-USC Medical Center
Connie Olson, RN
(213) 343-8279

123. HIV Wasting Treatment: Oxandrolone

Title:

BTG/OXN-95-002: A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Safety and Efficacy of Oxandrolone on Body Weight/Composition in HIV-Infected Male Patients

Type of treatment:

Oxandrolone: anabolic steroid

Purpose:

To see if oxandrolone is safe and effective in male patients experiencing unintentional weight loss. To see which dose of oxandrolone is most effective and safest.

About the study:

Patients are assigned by chance to receive one of three doses of oxandrolone or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. Oxandrolone is a pill and taken by mouth. Study visits are every two weeks for the first month, then every four weeks. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- At least 18 years old
- 10-20% unintentional weight loss from a documented baseline weight
- Male patients only
- If patients are taking antiretroviral therapy, they must be on stable antiretroviral therapy for at least 6 weeks

Not allowed:

- Female patients
- 5% or more weight loss during the month prior to enrollment
- Any current AIDS-related opportunistic infections
- Treatment with any appetite-stimulating agents such as megace, marinol, prednisone or any other anabolic steroids, such as testosterone, nandrolone, growth hormone, within four weeks of study entry
- Current alcohol or substance abuse
- Any cancers other than KS which require systemic chemotherapy
- Patients requiring tube feeding
- Chronic diarrhea or fever
- Any eating disorder such as anorexia nervosa or bulimia, or any untreated thrush or oral herpes which interferes with eating

Location:

Beer Medical Group
Heather Robertson
(213) 937-5151

Cedars-Sinai Medical Center
Jacqui Pitt, RN
(310) 855-3755

Kaiser San Francisco - HIV Research Unit
Joseph Thatcher, RN, MSN
(415) 202-2529

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

San Francisco VA Medical Center
Mae Pang, RN, MS
(415) 750-2005

124. HIV Wasting Treatment: Megace, Testosterone

Title:

ACTG 313: A Double-Blind, Randomized Comparison Phase II Trial of Megestrol Acetate and Testosterone Enanthate in Combination Versus Megestrol Acetate Plus Testosterone Enanthate Placebo in Human Immunodeficiency Virus (HIV)- Associated Wasting

Type of treatment:

Megace: appetite stimulant
Testosterone: steroid

Purpose:

To see if the predominant gain in fat rather than lean body mass that occurs when people take megestrol acetate (Megace) is improved by treatment with megace and testosterone.

About the study:

Patients are assigned by chance to receive megace plus testosterone or to receive megace plus placebo. Neither patients nor their doctors will know if they are receiving testosterone until the end of the study. Megace is a liquid and is swallowed, while testosterone and its placebo are injections given into a muscle. After 12 weeks, all patients will take megace and real (no placebo) testosterone injections for an additional 12 weeks. Study visits (injections) are every two weeks and the study lasts 24 weeks. Patients will receive body composition analysis tests as part of the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Documented weight loss of >10% of pre-illness weight
- Blood testosterone levels must be normal for gender
- Patients on antiretroviral treatment must be on stable (no changes) treatment for at least 30 days prior to study entry

Not allowed:

- Any acute opportunistic infection within 30 days prior to study entry
- A weight gain of 3% or more during the preceeding four weeks
- Use of any interleukins, interferons, or anabolic treatments such as thalidomide, marinol, megace, growth hormone, steroids within 30 days of study entry
- Use of ketoconazole within 30 days of study entry
- Any history of allergy or sensitivity to megace or testosterone
- Diabetes mellitus
- Diarrhea defined as four or more liquid stools per day while using antidiarrheal medication
- Current use of systemic chemotherapy for any cancer other than KS
- Patients requiring total parenteral nutrition or tube feeding
- Severe nausea/vomiting
- Use of anticoagulant medications
- Patients with current or past cardiomyopathy or congestive heart failure
- Women who are pregnant or breastfeeding

Location:

UCSF AIDS Program at SFGH/ACTU
Carol Arri, RN
(415) 476-9296 ext. 351

New

125. HIV Weight Loss in Men: Nandrolone Decanoate, Exercise

Title:

Nandrolone Decanoate and Resistance Training for Augmenting Muscle Mass in Patients with HIV

Type of treatment:

Exercise: weight training
Nandrolone Decanoate: anabolic steroid

Purpose:

To see if weight training combined with anabolic steroid treatment is more effective in gaining muscle mass than with an anabolic steroid alone.

About the study:

All patients will receive nandrolone decanoate and will be assigned by chance to train with weights or to not train with weights. Nandrolone is given by injection into a muscle once a week for 12 weeks. Those patients assigned to exercise will work out three times a week with a professional trainer and will travel to the USC facility, just east of downtown Los Angeles. After 12 weeks of nandrolone treatment, all patients will have the opportunity to receive instructions about weight training and be followed for an additional 12 weeks. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: between 50 and 400
- HIV positive male patients only
- At least 18 years old
- Less than 5% total weight loss
- Patients with less than 200 T-cells must be taking PCP prophylaxis
- Patients must be receiving at least 2 antiretroviral treatments, one of which must be either 3TC or a protease inhibitor
- Willingness to work out three times a week and travel to the USC facility

Not allowed:

- Female patients
- Prior diagnosis of wasting OR more than 5% weight loss in the preceding year
- No active AIDS defining infections or cancers
- Currently using Megace
- Patients with cardiac disease or diabetes requiring treatment

- Chronic active hepatitis B or C
- Use of immunomodulators (interferons, interleukins, thalidomide, corticosteroids)
- Previous use of anabolic steroids or human growth factor
- Prostate enlargement

Location:

LAC-USC Medical Center
Connie Olson, RN
(213) 343-8279

126. HIV Weight Loss in Women: Nandrolone Decanoate

Title:

ACTG 329: A Randomized, Double-Blind, Placebo-Controlled, Phase I/II Trial of Nandrolone Decanoate in Women With HIV-Associated Weight Loss

Type of treatment:

Nandrolone Decanoate: steroid

Purpose:

To see if nandrolone decanoate is a safe and effective treatment for women experiencing HIV-associated unintentional weight loss.

About the study:

Women will be assigned by chance to receive nandrolone decanoate or placebo. Nandrolone decanoate is given by injection into a muscle. Neither patients nor their doctors will know which they are receiving until the study ends. After 12 weeks, all patients will be eligible to receive open-label (real) nandrolone decanoate for an additional 12 weeks. Injections are given every two weeks. The study lasts 24 weeks. Patients in this study will receive body composition tests.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 13 years old
- Female
- Documented weight loss of >5% within the previous 12 months
- Patients taking antiretroviral therapy must have been on stable (no changes) therapy for at least 30 days prior to study entry

Not allowed:

- Males
- Active opportunistic infection or other major illness within 30 days of study entry
- Use of other anabolic therapy, such as steroids, growth hormone, thalidomide, megace, marinol, within 30 days of study entry
- Starting antiretroviral therapy within 30 days of study entry
- Women who are pregnant or breastfeeding
- Patients with a persistent palpable dominant breast mass at study entry that has not been evaluated
- Any history of cervical cancer. Patients with a high grade SIL or CIN2 or worse Pap smear are not eligible
- Diabetes mellitus
- Current or past congestive heart failure or cardiomyopathy
- Any condition requiring anticoagulation therapy while on study
- Persistent diarrhea, nausea, vomiting or impaired oral intake

Location:

UCSD Treatment Center
Anne French, RN
(619) 543-8080, ext. 238

UCSF AIDS Program at SFGH/ACTU
Carol Arri, RN
(415) 476-9296 ext. 351

New

127. HIV Wasting Treatment in Women: Oxandrolone

Title:

BTG/OXN-95-007: A Phase III Randomized, Double Blind Placebo Controlled Study to Determine the Safety and Efficacy of Oxandrolone on Body Weight and Composition in HIV-Infected Women

Type of treatment:

Oxandrolone: anabolic steroid

Purpose:

To see if oxandrolone is safe and to see its effect on body weight and body composition in HIV-infected women.

About the study:

Patients are assigned by chance to receive one of two doses of oxandrolone or placebo. Oxandrolone is in pill form and two pills are taken every day before breaffast. Neither patients nor their doctors will know which they are taking until the study ends. After 12 weeks, all patients will take open label (real) oxandrolone. Initially study visits will be once a week, then once a month. The study lasts 24 weeks

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Female patients only
- Documented involuntary weight loss of 10 - 20 % of average body weight
- If taking antiretroviral medications, must be on a stable dose for at least six weeks prior to enrollment

Not allowed:

- Male patients
- Weight loss of greater than 5% during the month prior to enrollment
- Current opportunistic infections
- Use of appetite stimulants or weight promoting agents within four weeks of study entry; such as Megace, Marinol, prednisone, testosterone, growth hormone
- Active alcohol or substance abuse
- Anorexia nervosa or bulimia
- Any cancers other than KS which require chemotherapy
- Ongoing chronic diarrhea defined as more than 3 liquid stools per day at least 4 days per week for more than 2 weeks
- Women who are pregnant or breastfeeding

Location:

AIDS Healthcare Foundation
Heather Churchill, RN
(213) 913-3953

128. HIV Weight Loss: Observational

Title:

Energy Balance and Wasting Syndrome

Type of treatment:

Observational: none

Purpose:

To study metabolism and collect data from patients with HIV weight loss.

About the study:

Patients joining this study should be experiencing some weight loss associated with HIV disease. The study requires two outpatient visits and will have to spend four days in the hospital for metabolic rate testing. The study lasts three weeks and patients will be paid $400 for completing the study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive

Location:

San Francisco VA Medical Center
Mae Pang, RN, MS
(415) 750-2005

129. Nutrition in Women with HIV: Observational

Title:

Nutritional Assessment of Women Living with HIV

Type of treatment:

Observational: none

Purpose:

To learn about the effect of HIV disease on women's body composition (fat, muscle and bone). To learn how HIV disease affects the amount of energy used up by a woman's body when it is at rest. To learn how HIV disease affects women's eating habits. To compare these factors in women and men.

About the study:

This study consists mainly of body measurements and interviews. Every six months, patients come into the clinic for a two-hour study visit. Tests and measurements are done to determine body composition and patients are asked questions about the kind and amount of food they eat. Nutritional counseling is offered to patients who want it. The study lasts for an indefinite length of time. Patients are paid $25 at each visit.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Female

Location:

UCSF/SFGH Endocrinology
Viva Tai, RD, MPH
(415) 206-4090

130. Human Herpes Virus 8 Project: Developmental

Title:

Pilot Project for the Development of a Branched-Chain DNA Assay for Human Herpes Virus 8

Type of treatment:

Observational: none

Purpose:

To see whether a laboratory test can be developed to detect and measure the amount of human herpes virus 8 in patients' blood samples.

About the study:

Patients with KS will be asked to provide one blood sample at one visit. Patients will be paid $25 for this one visit.

Required:

- CD4 cell (T-cell) range: not specified
- At least 13 years old
- Must have a diagnosis of Kaposi's sarcoma

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-6796

131. HIV Transmission: Educational Intervention

Title:

HIV Prevention Intervention Study with an Embedded Observational Substudy

Type of treatment:

Observational: none

Purpose:

To see how well two different educational approaches help heterosexual/bisexual couples affected by HIV deal with problems they experience in protecting themselves from HIV transmission. To identify biological factors that might be associated with prevention of HIV transmission.

About the study:

The main study is one year long and consists of a brief intensive intervention (one hour per week over four weeks) followed by three 30-minute booster sessions over a period of five months. Couples will be assigned by chance to receive intensive counseling for both partners or intensive counseling for the infected partner, with support and referrals for the negative partner. Participants will be seen at various locations throughout the Bay area. Every 6 months, participants will also be seen for a 2-hour study visit with interviews and lab tests for HIV, STD and pregnancy. The biological substudy consists of one visit at a clinic for a brief interview, blood draw and physical exam. The study lasts three years. Participants are paid for their participation.

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive with an HIV-negative partner of the opposite sex or HIV negative with an HIV-positive partner of the opposite sex
- Sexually active with that partner
- At least 18 years old

Not allowed:

- Unable to speak English or Spanish

Location:

California Partners Study
Pauline Acosta
(800) 262-2430

132. HIV Infection and the Central Nervous System: Observational

Title:

HIV Infection & Cognition: Observational

Type of treatment:

Observational: none

Purpose:

To learn more about the effects of HIV on the brain and thought processes.

About the study:

Participants are given a series of special examinations including a blood test, neurological examination, cognitive tests, brain wave recordings from metal disks placed on the scalp, and a magnetic resonance imaging (MRI) test. An MRI involves lying on a narrow bed in a recording tube in an MRI machine for about 2 hours. Participants are offered sedatives for this process, but must have an escort to accompany them home if they choose to be sedated. There are four study visits in a series and one series every 9 to 18 months. Results of the tests are made available to the participants and their physicians, and participants are paid for their time.

Required:

- CD4 cell (T-cell) range: 200 or below
  -or-
- HIV negative -or-
- HIV positive with cognitive impairment

Not allowed:

- Past or current toxoplasmosis or cryptococcal meningitis

Location:

Department of Psychiatry, UCSF / VA
Lynn Nielsen-Bohlman, PhD
(415) 476-7650

133. Pharmacokinetics: INH

Title:

Pharmacokinetics of Antituberculous Agents in HIV

Type of treatment:

Isoniazid: antimycobacterial

Purpose:

To learn how INH is absorbed and processed in the body. To compare the way this happends in men and women, and in people with AIDS and those who do not have HIV Infection.

About the study:

This study is open to men and women with AIDS and men and women who do not have HIV infection. All patients take 300 mg. of INH every day for five days. Blood is drawn to measure the amount of INH in the blood. A small tube is inserted into the lungs to collect fluid and cells in order to measure the amount of INH that is absorbed into the lungs. There are several short study visits and one six-hour study visit. Patients are paid $350 for completing the study.

Required:

- CD4 cell (T-cell) range: not specified
- At least 18 years old
- AIDS or HIV-negative
- Negative PPD (skin test) for TB, negative chest x-ray for patients with HIV

Not allowed:

- Diarrhea, abdominal pain or cramping, nausea, vomiting

- HIV positive, but not meeting the CDC definition for AIDS
- Women who are pregnant or breast-feeding

Location:

UCSF Infectious Diseases Research
Elaine McKenna
(415) 476-2308

New

134. Pharmacokinetics: SCH56592

Title:

C96-190-01: Pharmacokinetic Drug Interaction Study with Zidovudine/ Lamivudine and Protease Inhibitors in HIV-Infected Patients

Type of treatment:

SCH 56592: antifungal

Purpose:

To see if there are any drug interactions when SCH 56592 is given to HIV-infected patients who are taking a nucleoside analog drug and a protease inhibitor. To see if SCH 56592 is safe to take in combination with AZT, 3TC and protease inhibitors.

About the study:

Patients entering this study must be taking AZT, 3TC and either indinavir or ritonavir. They may not take any other drugs except those given as part of the study. All patients will be given SCH 56592 to take by mouth for 14 days. There will be two separate overnight hospital stays (4 days, 3 nights) and up to six outpatient visits lasting about an hour or less. The study lasts approximately 19 days. Patients will be paid $600 for completing the study

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: not applicable
- HIV positive
- Between 18 and 45 years old
- Must be taking AZT, 3TC and either indinavir or ritonavir

Not allowed:

- Any other medications besides AZT, 3TC, indinavir or ritonavir without approval from the investigator
- No alcohol or caffeine during the study
- Any current acute opportunistic infections
- Prior hepatitis B or C
- Liver, kidney or heart disease
- Women who are pregnant or breastfeeding

Location:

UCSF Drug Research Unit at SFGH
Suzanne Brody, Pharm.D.
(415) 502-5307

135. Pharmacokinetics in Women in Labor: Nevirapine

Title:

Pediatric ACTG 250: A Phase I Study of Safety and Pharmacokinetics of Nevirapine in HIV-1 Infected Pregnant Women and Neonates Born to HIV-1 Infected Mothers

Type of treatment:

Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To find the highest dose of nevirapine which is safe to give to HIV-infected women during labor.

About the study:

This study involves three groups of mothers and their infants. The first group of mothers receives a single dose (100 mg) of nevirapine during active labor (the infant does not receive nevirapine). All mothers and their infants in this study have blood tests for 7 days after the infant is born to watch for side effects. When a safe dose is found, the second group of mothers receives a single dose of nevirapine during labor, and their infant receives a single dose of nevirapine at birth. The third group of mothers receives a single dose of nevirapine during labor and their infants receive multiple doses of nevirapine at birth, if necessary. Nevirapine is taken by mouth. The study lasts 6 - 8 weeks for mothers, and 6 months for infants.

Required:

- CD4 cell (T-cell) range: not specified
- Mothers must be HIV positive
- Must be at least 34 weeks pregnant

Not allowed:

- Active opportunistic infection or serious bacterial infection
- Intrauterine growth retardation
- Prior treatment with nevirapine
- Anti-HIV therapy other than AZT
- Participation during this pregnancy in a therapeutic or vaccine perinatal trial (ACTG 076, ACTG 233, ACTG 249)

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Joel Miller
(415) 206-8919

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

136. Mother-Newborn Transmission Prevention: HIVIG, IVIG, AZT

Title:

Pediatric ACTG 185: Phase III Randomized, Double Blind, Controlled Study of the Use of HIVIG for the Prevention of Maternal-Fetal Transmission in Pregnant Women and Newborns Receiving Zidovudine (ZDV).

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
HIVIG: immune modulator
IVIG: immune modulator

Purpose:

To find out if it is better and safer for HIV+ pregnant women and their infants to take HIVIG and AZT or IVIG and AZT.

About the study:

Patients are assigned by chance to receive IVIG and AZT or HIVIG and AZT. Neither the patients nor their doctors know whether they are taking IVIG or HIVIG until the study ends. The study will last at least two years. IVIG and HIVIG are given by infusion into a vein. AZT is taken by mouth, four times a day. Women will receive infusions of HIVIG or IVIG every month. Infants will receive an infusion only once; at birth, infants will receive AZT by mouth for six weeks.

Required:

- CD4 cell (T-cell) range: 500 or below
- HIV+ pregnant women
- At least 4 months and less than 7 1/2 months pregnant
- Currently taking AZT

Not allowed:

- Ever taken any anti-HIV therapy other than AZT during this pregnancy
- Ever taken IVIG or HIVIG or anti-HIV vaccines during this pregnancy

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Joel Miller
(415) 206-8919

LAC-USC Medical Center - Maternal Child Program
Nancy Creighton, RN
(213) 226-5068

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

137. HIV Infection in Pregnant Women: ddI

Title:

Pediatric ACTG 249: A Phase I Trial to Evaluate Didanosine (ddI) in HIV-1 Infected Pregnant Women

Type of treatment:

ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if ddI is safe and effective for treating women in their third trimester of pregnancy. To see how ddI is absorbed and processed by the bodies of pregnant women. To determine the effects of ddI on the newborn infant of mothers treated with ddI during the third trimester.

About the study:

All patients will receive a one-hour infusion (injection into a vein) of ddI. Patients will then take ddI by mouth twice a day until the onset of labor. During labor, patients will receive another infusion of ddI until delivery.

Study visits are every two weeks and patients will be in this study from 3 to 5 months.

Required:

- CD4 cell (T-cell) range: between 50 and 350
- HIV positive
- At least 13 years old
- Fetal age of at least 26 weeks but not more than 36 weeks, based on last menstrual history
- Not able to take AZT due to side effects or failure of AZT

Not allowed:

- Past stillbirth, neonatal death or a previous infant with malformations
- Current obstetrical complications
- Expected multiple birth
- Past maternal medical complications such as, malabsorption, pancreatitis, neurological complications including peripheral neuropathy, CMV requiring ganciclovir or foscarnet
- Current use of steroids, INH (isoniazid), IV pentamidine or current regular alcohol use
- Current antiretroviral therapy with anything other than ddI

Location:

LAC-USC Medical Center - Maternal Child Program
Nancy Creighton, RN
(213) 226-5068

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

New

138. HIV Infection in Women in Labor: AZT

Title:

Pediatric ACTG 324: A Phase I Trial of the Pharmacokinetics and Tolerance of Oral Zidovudine Administered to HIV-1 Infected Pregnant Women During Labor and Delivery

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how AZT is processed by the body when taken by mouth in HIV-positive women during labor and delivery

About the study:

This study invloves two groups of patients. At the onset of labor, the first group of patients will take three doses of AZT, three hours apart. Blood samples will be taken after each dose. After the last dose of AZT is taken by mouth, patients will take AZT by infusion into a vein until delivery of the baby. If no problems occur with the first group of patients, the second group will follow the same plan, except they will continue taking AZT by mouth after the third dose, rather than taking AZT by infusion into a vein. Patients will return to the clinic one week after delivery, and again four to eight weeks and six to eight months after delivery. Blood samples will be taken at each visit.

Required:

- CD4 cell (T-cell) range: not applicable
- Mothers must be HIV positive
- Mothers must be at least 34 weeks pregnant, confirmed by pelvic exam or ultrasound
- Prior treatment with AZT for at least 28 days during this current pregnancy

Not allowed:

- Use of any antiretroviral other than AZT
- Any active opportunistic or other serious infection at the time of study entry
- Intrauterine growth retardation
- Elective cesarean section
- Participation in any other perinatal treatment trial during this pregnancy

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Joel Miller
(415) 206-8919

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

139. HIV Exposure in Premature Infants: AZT

Title:

Pediatric ACTG 331: The Safety, Tolerance and Pharmacokinetics of Zidovudine in Premature Infants Exposed to HIV

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To learn how AZT is absorbed and processed in premature infants exposed to HIV. To learn about the safety of using AZT in premature infants.

About the study:

Infants who are born prematurely and who will receive AZT as part of their clinical care will be enrolled in this study. The study requires nine blood samples collected over 30 days, and some additional clinical laboratory tests collected over 12 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- Premature infant (34 weeks gestation or less)
- Less than 5 days old
- Infant should receive AZT, in the opinion of the primary care provider

Not allowed:

- Life-threatening illnesses
- Infant not expected to survive beyond six weeks

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Joel Miller
(415) 206-8919

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

140. HIV Infection in Children: AZT, ddI, 3TC

Title:

Pediatric ACTG 300: A Randomized, Comparative Study of Zidovudine (ZDV), Lamivudine (3TC) vs. The Better of ddI Monotherapy vs. Zidovudine Plus ddI in Symptomatic HIV-1 Infected Children.

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare the combination of AZT and 3TC to either ddI alone, or ddI + AZT in children with HIV. (There is a another study that compares ddI to AZT + ddI. This study will finish soon, and the findings will be applied to this study).

About the study:

Patients are assigned by chance to receive AZT plus 3TC, or ddI alone, or ddI plus AZT. Neither the patients, their parents, nor the doctors will know which they are receiving until the study ends. All of the medications are given by mouth, either as liquids or pills. The study requires once a month visits, and lasts 2 to 4 years.

Required:

- CD4 cell (T-cell) range: not specified
- Between 90 days and 15 years old
- For babies under 18 months old, at least 2 positive viral tests
- Some symptoms of HIV-infections or AIDS
- Must not have received more than 56 days of antiretroviral therapy in the past

Not allowed:

- Currently have cancer
- Pregnant girls

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

141. HIV Infection in Infants: AZT, ddI

Title:

Pediatric ACTG 239: A Phase I Evaluation of the Safety and Toxicity of Zidovudine and Didanosine in Combination in HIV-Infected or Exposed Infants, and, A Phase II Study of the Effect of Didanosine vs. Combination Therapy with Zidovudine and Didanosine on CD4 Decline and Growth in Infants with HIV Infection

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

This is a two-part study. In the first part, researchers are trying to find the best dose of the drug ddI for studies of ddI plus AZT in infants. They will also learn more about the effects of both AZT and ddI on infants' bodies. In the second part of the study, researchers will compare the combination of AZT and ddI to ddI alone to see which is better to fight HIV in infants.

About the study:

The plan for the first part of this study is fairly complicated, and depends on whether the infants have received AZT or not. Please call the contact person below for more details. In the second part of the study, infants are assigned by chance to receive ddI alone or ddI plus AZT. Neither the parents nor the doctors will know which the infants are receiving until the study ends. The study lasts at least one year. Infants are monitored for physical growth and CD4 counts throughout the study.

Required:

- CD4 cell (T-cell) range: not specified
- For the first part of the study, infants must be less than 28 days old
- For the second part of the study, infants must be less than or equal to 90 days old
- Must have laboratory tests showing that they have been infected with HIV
- Parent's permission

Not allowed:

- Ever had pancreatitis
- Unstable health at current time

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

142. HIV Infection in Children: bis-POM PMEA

Title:

Pediatric ACTG 310: A Phase IA Single Dose Pharmacokinetics and Safety Study of the Oral Antiviral Compound bis-POM PMEA (Adefovir Dipivoxil) in Children with HIV-1 Infection

Type of treatment:

bis-POM PMEA: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if bis-POM PMEA is safe for children to take and to see which dose

is best tolerated. To see how bis-POM PMEA is processed by childrens' bodies.

About the study:

Children entering this study will be given the lowest of two doses of bis-POM PMEA. bis-POM PMEA is a pill and taken by mouth. Patients will only take the medication once and will only be studied once. After safety data has been gathered, the next patients will take the higher dose of bis-POM PMEA. The study lasts one day and will last all day long so timed blood and other tests can be taken.

Required:

- HIV positive
- Less than 18 years old

Not allowed:

- Patients taking any of the following must discontinue them beginning 72 hours before and continuing 72 hours after the study dose: any other antiretroviral agents; other investigational agents; immunomodulators; HIV vaccines, Bactrim/Septra or Dapsone, acyclovir, ganciclovir, foscarnet, pentamidine Amphotericin B
- Females who are pregnant

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415)476-6480

143. HIV Infection in Children: rIL-2

Title:

Pediatric ACTG 299: Phase I/II Trial of Recombinant Interleukin-2 in Symptomatic Human Immunodeficiency Virus-Infected Children

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To see if interleukin-2 is safe and effective for treating children who are HIV-infected. To find the highest dose of interleukin-2 that is safest for children to take.

About the study:

This is a dose escalating study. This means that the first patients to enter the study wil receive the lowest dose of interleukin-2. If this dose is tolerated with no bad side effects, the next group of patients will receive the next highest dose level and so forth until the highest dose that is tolerated with no bad side effects is found (Part A). Once the maximum tolerated dose has been determined, additional patients will be enrolled to receive that dose (Part B). Interleukin-2 is given as an infusion into a vein. Children will receive a continuous infusion for five days in a row every eight weeks. This is called a cycle and children will complete three cycles. Those children who participated in Part A and did not receive the maximum tolerated dose of interleukin-2 will be eligible to participate in Part B to receive that dose. Parts A and B both last 44 weeks.

Required:

- CD4 cell (T-cell) range:
  age 3-5 years: 500 - 1000
  age 6-12 years: 200 - 500
- Viral load range: not applicable
- HIV positive
- Between 3 and 12 years old. Patients are eligible if they enter the study prior to their 13th birthday
- Patients must be receiving the best available antiretroviral therapy for at least one month and not more than 12 months prior to study entry
- Children must have symptomatic HIV infection

Not allowed:

- Any active opportunistic infection
- Any steroids or other immunosupressive therapy
- Current polyclonal or monoclonal antibody therapy
- Current use of IVIG
- Females who are pregnant

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

New

144. HIV Infection in Children: d4T, ddI

Title:

Pediatric ACTG 327: Trial of Stavudine (d4T) Plus Didanosine (ddI) in Children on Long-Term Stavudine Monotherapy, and Stavudine Versus Stavudine Plus Didanosine in Children on Long-Term Zidovudine Monotherapy: A Rollover Protocol for ACTG 240 Participants and Children Receiving Prescription Zidovudine

Type of treatment:

d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare the safety and effectiveness of taking d4T and ddI together compared to taking d4T alone.

About the study:

This study involves two groups of children: those who were previously enrolled in ACTG 240, and those who have received more than six months of AZT therapy by prescription. Children previously enrolled in ACTG 240 will receive d4T and ddI. Those children who have received more than six

months of AZT therapy by prescription will be assigned by chance to receive d4T plus ddI or to receive d4T plus a placebo. Neither the children in this group nor their doctors will know which they are taking until the study ends. d4T and ddI are taken by mouth. Study visits are once a month. Blood samples are drawn at each visit. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 6 months and 10 years old
- Enrolled in ACTG 240 and still on treatment, or taking AZT therapy for at least six months

Not allowed:

- Enrolled in ACTG 240 but not taking treatment
- Any acute opportunistic infections requiring treatment
- Prescription AZT children may not have taken more than six weeks of d4T or ddI in the past
- Use of any other antiretroviral drugs, immunomodulators or any other investigational drug during the study
- Any cancers requiring chemotherapy

Location:

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

New

145. HIV Infection in Children: Ritonavir, AZT, 3TC, d4T

Title:

Pediatric ACTG 338: A Phase II Rolling Arm Master Protocol (PRAM) of Novel Antiretroviral Therapy in Stable Experienced HIV-Infected Children

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To learn which of three combinations of anti-HIV drugs does the best job of reducing the amount of HIV in the blood of children in the study.

About the study:

Children are assigned by chance to receive AZT + 3TC OR d4T + ritonavir OR AZT + 3TC + ritonavir. Neither patients nor their doctors will know which they are taking until the study ends. Study visits are once a month. Blood samples are taken at each visit. As more information is available, other combinations of anti-HIV drugs will be included in the study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 24 months and 17 years old
- Must have been taking antiretroviral therapy for at least four months prior to the study
- Females of childbearing potential must have a negative pregnancy test

Not allowed:

- Current use of any of the treatment combinations that are part of the study
- Pregnancy
- Any active opportunistic infections, cancers or serious bacterial infections

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

New

146. HIV Infection in Infants and Children: 1592U89

Title:

Pediatric ACTG 330: A Phase I Safety and Pharmacokinetic Study of 1592U89 Alone and in Combination with Other Antiretroviral Agents in Infants and Children with HIV Infection

Type of treatment:

1592U89: antiretroviral
3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see which dose of a new experimental drug, 1592U89, when taken alone and in combination with other anti-HIV drugs, is the safest and has the best effect on reducing the amount of HIV in the blood.

About the study:

All patients will receive 1592U89 for 12 weeks. For the first six weeks, patients will take a low dose of 1592U89. If there are no bad side effects, patients will take a higher dose for the next six weeks. After 12 weeks, patients will be assigned by chance to take 1592U89 in combination with either AZT, d4T, ddI or 3TC for another 12 weeks. Patients and their doctors will know which drugs they are taking. There are no placebos in this study. Study visits are every two weeks. The study lasts six months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 3 months and 13 years old

Not allowed:

- Use of any anti-HIV drugs (except 1592U89, AZT, ddI, d4T, 3TC), immunomodulators or other investigational drugs during the study
- Serious opportunistic infections or cancers requiring treatment
- Chronic diarrhea or vomiting

Location:

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

New

147. HIV Infection in Newborns: 1592U89, AZT

Title:

Pediatric ACTG 321: Phase I Study of Safety, Tolerance, and Pharmacokinetics of 1592U89 with Standard Zidovudine (ZDV) Therapy in Neonates Born to HIV-1 Infected Mothers

Type of treatment:

1592U89: antiretroviral
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To find out the amount of 1592U89 there is in the blood of newborn babies who receive a single dose of 1592U89 in addition to AZT. To compare the safety of different doses of 1592U89.

About the study:

This is a dose escalating study. This means that the first group of patients entering the study will receive the lowest dose of 1592U89. If no bad side effects are seen, the next group of patients will receive a higher dose of 1592U89. This study consists of two parts: Part 1 and Part 2. Part 1 has two groups: A and B. Group A is for infants 0 - 72 hours of age; Group B is for infants 21-28 days of age. Both groups will receive a single dose of 1592U89 and AZT on the first day. They will continue to take AZT four times a day for six weeks. 1592U89 and AZT are taken by mouth. Five study visits are required for Part 1. Part 2 is a study of multiple doses of 1598U89 in infants 0-72 hours of age. All patients will take 1592U89 and AZT every day for six weeks. Six study visits are required. The study lasts eight weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Infants born to HIV-infected mothers
- Part 1A: Infants between birth and 72 hours old
- Part 1B: Infants between 21 and 28 days old

Not allowed:

- Infants with major congenital abnormalities
- Exposure (through the mother) to any protease inhibitors or NNRTIs
- Any serious infections requiring treatment during the study

Location:

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

148. Infant Immune Response: Pneumococcal Conjugate Vaccine

Title:

Pediatric ACTG 292: A Double Blind, Placebo-Controlled Trial of the Safety and Immunogenicity of a Seven Valent Pneumococcal Conjugate Vaccine in Presumed HIV-Infected Infants

Type of treatment:

Pneumococcal vaccine

Purpose:

To learn if infants who receive a pneumococcal conjugate vaccine have more of a reaction at the site of injection and in the body than those who receive placebo. To learn if infants who receive a pneumococcal conjugate vaccine develop more pneumococcal antibody than those receiving placebo.

About the study:

Patients are assigned by chance to receive either pneumococcal conjugate vaccine or placebo. Neither parents nor their doctors will know which they are receiving until the study ends. The study lasts until the infant is 2 years old. There are 10 study visits. Injections will be given at the beginning of the study, 2 months after the study begins, 4 months after the study begins, and at 15 months of age. All infants will receive the licensed pneumococcal polyvalent vaccine at 24 months of age.

Required:

- CD4 cell (T-cell) range: not specified
- Between 56 and 180 days old
- Presumed HIV infection

Not allowed:

- Use of blood products (such as IVIG, VZIG, HbIG, transfusions) within 56 days before joining the study
- Vaccination with pneumococcal vaccine
- Congenital immunoglobulin deficiency, SS or SC hemoglobinopathy, or asplenia
- Use of any immunosuppressant drug (including prednisone) for more than 6 weeks

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

149. Bacterial Infection Prevention in Children & Adolescents: Antibiotics

Title:

Pediatric ACTG 254: A Randomized, Phase II/III, Double Blind, Placebo Controlled, Two-armed Study of Micronized-Atovaquone and Azithromycin as Compared to Trimethoprim-Sulfamethoxazole in the Prevention of Serious Bacterial Infections When Used in Children Aged 2-18 Years with HIV Infection.

Type of treatment:

Atovaquone: antibacterial
Azithromycin: antibacterial
Trimethoprim-Sulfamethoxazole: antibacterial

Purpose:

To find out if taking the drugs atovaquone and azithromycin together is as good or better than taking Septra alone in preventing serious bacterial infections.

About the study:

Patients are assigned by chance to receive atovaquone and azithromycin and placebo or Septra and placebo. All drugs are taken by mouth. Neither the patients nor their doctors know which drugs they are taking until the study ends. The study lasts two years.

Required:

- CD4 cell (T-cell) range: not specified
- Between 2 and 18 years old
- HIV positive
- At risk for developing PCP

Not allowed:

- Active PCP
- Past use of atovaquone or azithromycin
- Being treated for MAC, toxoplasmosis, tuberculosis, cryptosporidiosis or microsporidiosis

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

150. Congenital CMV Infection: Ganciclovir

Title:

Evaluation of Ganciclovir (DHPG) for the Treatment of Symptomatic Congenital Cytomegalovirus Infections

Type of treatment:

Ganciclovir, IV: antiviral

Purpose:

There is currently no licensed drug to treat congenital CMV infection. This study will see if treatment with ganciclovir (DHPG) is better or worse than no drug treatment in infants. The study will look at the risks versus the benefits of using either ganciclovir or not treating with the medication.

About the study:

Babies with symptomatic congenital CMV infection will be assigned by chance to receive ganciclovir or to receive no medication. Ganciclovir is given by infusion (into a vein) for one hour twice a day. Infusions will be given

for a period of six weeks. After six weeks of treatment, babies will be examined at two and four weeks for eye and neurologic symptoms. Long-term studies will be performed at six month intervals (twice) then annually. Babies assigned to no treatment will be monitored and evaluated the same as babies receiving treatment.

Required:

- Between two weeks and one month old
- Confirmed CMV in cultures of throat, urine and white blood cells
- Evidence of CNS involvement such as microcephaly, abnormal CSF for age, chorioretinitis, hearing defects

Not allowed:

- Gestational age less than 32 weeks
- Mild symptomatic or asymptomatic congenital CMV infections
- Weight leas than 1,200 grams at birth
- Currently using other antivirals or immune globulin

Location:

LAC-USC Medical Center - Maternal Child Program
Richard Erickson, RN
(213) 226-5068

151. Herpes Simplex/Zoster Infections in Children: Valaciclovir

Title:

Pediatric ACTG 253: A Phase I Trial to Evaluate the Pharmacokinetics, Safety and Tolerance of Valaciclovir HCl in HIV-1 Infected Children (up to 12 Years of Age) with Herpes Simplex Infections or Varicella/Zoster Infections

Type of treatment:

Valaciclovir: antiviral

Purpose:

To see if valaciclovir is safe and well-tolerated for children with herpes infections. To see how valaciclovir is processed by the body and to see what dose is best for children to take.

About the study:

This is a dose-ranging or dose-escalating study. This means that the first group of children with herpes simplex will receive the lowest dose of valaciclovir. If no bad side effects are observed, the next group of children with herpes simplex will receive a higher dose of valaciclovir. Based on the safety data provided by these two groups, an appropriate dose of valaciclovir will be selected to be studied in children with varicella or zoster. Valaciclovir is a pill and taken by mouth. Study visits are required on days 0, 1, 2, 4, 9 and 40. The study lasts approximately 40 days.

Required:

GENERAL
- HIV positive
- Between 4 and 12 years old
- Children on antiviral therapy must have been on the same therapy for at least two weeks prior to study entry

HERPES SIMPLEX
- CD4 cell (T-cell) range: 100 or more
- Localized herpes simplex infection

HERPES ZOSTER
- CD4 cell (T-cell) range: 100 or more
- Onset of zoster within 72 hours of study entry

HERPES VARICELLA
- CD4 cell (T-cell) range: 250 or more
- Onset of varicella within 48 hours of study entry

Not allowed:

- Any AIDS diagnosis (varicella patients only)
- More than 48 hours after onset of lesions (varicella patients only)
- More than 72 hours after onset of lesions (zoster patients only)
- Children with evidence of zoster dissemination

Location:

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

152. Measles Vaccine in Children: Measles vaccine

Title:

Pediatric ACTG 225: A Phase II, Comparative Study of Seroconversion of Single-Dose and Two-Dose Measles Vaccination in HIV-Infected and HIV-Uninfected Children: A Multicenter Trial of the Pediatric AIDS Clinical Trials Group

Type of treatment:

Measles Vaccine: vaccine

Purpose:

To compare the seroconversion rates at 13 months of age in HIV-infected and in HIV-uninfected children who receive two doses of measles vaccine to those children who receive a single dose of measles vaccine. To compare the measles seroconversion rates in HIV-infected and HIV-uninfected children.

About the study:

Children who were born to HIV-infected mothers will be assigned by chance to receive one of two measles vaccine schedules; measles vaccine at 6 and 12 months of age or a single vaccine at age 12 months. All children will receive a measles vaccine at age 12 months. Children will enroll in this study at age 6 months and be followed for 24 months after their last vaccination. There are 14 study visits and the study lasts about three years.

Required:

- CD4 cell (T-cell) range: greater than or equal to 750
- Viral load range: not applicable
- HIV positive or negative
- Children 6 months of age but not over 7 months born to HIV-infected mothers
- Children should receive other childhood immunizations (other than measles) according to the recommendations of the American Academy of Pediatrics

Not allowed:

- Children with intercurrent illness and/or fever for seven days. May be rescreened when symptoms resolve
- Known exposure to measles within 14 days of study entry
- Children currently receiving IVIG or who have received any gamma globulin preparation within the previous six months.
- Children who received steroids within four weeks of study entry

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

153. Varicella Vaccine in HIV-Infected Children: Varicella Vaccine

Title:

Pediatric ACTG 265: Phase I/II Study of Safety and Immunogenicity of Live Attenuated Varicella Vaccine (VARIVAX) in HIV-Infected Children

Type of treatment:

Varicella Vaccine

Purpose:

To see if varicella vaccine is safe and effective in asymptomatic or mildly symptomatic HIV-infected children ages greater or equal to 1 year old and less than or equal to 8 years old.

About the study:

All children will receive varicella vaccine at the beginning of the study and at week 12. Those children who have are still negative for varicella at week 52 will receive a third varicella vaccine. There are 15 study visits and the study lasts three years.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: patients must have a minimum of two positive tests between greater than or equal to 1 year old and less than or equal to 8 years old
- Between 12 and 48 months old
- HIV positive
- Category N1 or A1 Clinical/Immunological status

Not allowed:

- Active infection within 72 hours of entry
- Fever greater than 101 within 72 hours of study entry
- Exposure to chicken pox and/or herpes zoster within four weeks prior to study entry
- Past occurrence of chicken pox or herpes zoster
- Any use of steroids within 30 days of study entry
- Treatment with any anti-herpes drug such as acyclovir, famciclovir, valaciclovir, ganciclovir, interferon and foscarnet within one week of study entry
- Use of IVIG, VZIG or blood product receipient within five months of study entry
- Current use of aspirin or expected use within six weeks of immunization
- Receipt of any other vaccine within 30 days of study entry

Location:

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

154. HIV Infection in Children and Adolescents: Observational

Title:

Pediatric ACTG 219: Pediatrics Late Outcomes Protocol

Type of treatment:

Observational: none

Purpose:

To learn about the long-term survival and quality of life of infants and children enrolled in ACTG studies. To learn more about the differences between HIV disease progression in HIV+ infants and children, and the effects of anti-HIV drugs in infants and children who are not HIV+.

About the study:

All patients get physical exams and blood tests on a regular basis. Information on health problems and quality of life are also collected. Patients will be in the study until their 21st birthday.

Required:

- CD4 cell (T-cell) range: not specified
- An infant, child or adolescent born to an HIV+ woman who was enrolled in an ACTG study while pregnant, or
- HIV+ infant or child ever enrolled in an ACTG treatment study

Not allowed:

- Children enrolled only in ACTG 220 or other observational studies

Location:

Children's Hospital of Los Angeles
Antonieta Sosa
(213) 668-2180

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center - Maternal Child Program
Lynn Fukushima, RN
(213) 226-5068

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

155. HIV Infection in Pregnant Women: Observational

Title:

Pediatric ACTG 255: A Study of Perinatal Transmission of Open Zidovudine-Resistant HIV Among Pregnant Women Treated with Zidovudine

Type of treatment:

Observational: none

Purpose:

To collect information about the effect of long-term AZT treatment on the occurence of AZT-resistant HIV in pregnant women and to see if AZT-resistant women will transmit HIV to their newborn babies.

About the study:

Women enrolling on this study will be asked questions about their medical history, and will be given a physical examination and laboratory tests three times before the birth of their child. After the infants are born, they are given four physical examinations and laboratory tests over the next two years. This is an observational study and patients will not be given drug treatment.

Required:

- CD4 cell (T-cell) range: 300 or below
- HIV positive
- Estimated to be 20-36 weeks pregnant
- At least 13 years old
- Taken AZT for at least six months prior to study entry, including continuous AZT use during current pregnancy

Not allowed:

- Current use of any antiretrovirals other than AZT
- Evidence of any pre-existing fetal malformation

Location:

LAC-USC Medical Center - Maternal Child Program
Nancy Creighton, RN
(213) 226-5068

UCLA Medical Center - Pediatrics
Leslie Spring
(310) 206-6369

UCSD Treatment Center - Pediatrics
Myrene Preston
(619) 543-8080 ext. 261

Compassionate Use, Expanded Access and Treatment IND Programs

Any new drug must be approved by the Food and Drug Administration (FDA) before it can be prescribed by a physician. FDA approval is based on the results of clinical trials. Many months or even years of clinical trials and analysis of the results may be needed before approval can be granted. Such a long testing period is necessary in order to learn about the safety and effectiveness of the drug. But sometimes, even during fairly early phases of testing, a drug may appear to have benefits which outweigh the risks of taking it before it has been fully tested. This is especially true when people cannot take any of the approved drugs, when approved drugs do not work, or for conditions which have previously been untreatable. Compassionate Use, Expanded Access and Treatment IND are programs which allow patients limited access to promising experimental treatments before they have been given full approval by the FDA. They are developed jointly by the FDA and the pharmaceutical company that makes the drug.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Albendazole	Microsporidiosis	SmithKline Beecham Compassionate Use Protocol	800-877-7074, x6454 (physician calls only)
AmBisome (liposomal Amphotericin-B)	cryptococcal meningitis failed standard Ampho-B	Fujisawa Pharmaceuticals Compassionate Use Program	847-317-0600 (physician calls only)
Azithromycin (Zithromax)	Toxoplasmosis Cryptosporidiosis Disseminated MAC	Pfizer Compassionate Use Protocol Pfizer Compassionate Use Protocol Pfizer Compassionate Use Protocol	800-742-3029 800-742-3029 800-742-3029
Cidofovir (HPMPC, Vistide)	CMV retinitis	Gilead Sciences Treatment IND	800-445-3235
Delavirdine Mesylate (Rescriptir)	HIV Infection CD4 count $\leq$ 300/mm^3	Pharmacia-Upjohn Expanded Access	800-779-0070
ddC (zalcitabine, HIVID)	HIV Infection (pediatric)	Hoffmann-LaRoche Open Label Program	800-285-4484
Foscarnet (Foscavir)	CMV other than retinitis	Astra Pharmaceuticals Compassionate Use Protocol	800-388-4148
Itraconazole oral solution	oral candidiasis (failed fluconazole)	Janssen Pharmaceuticals	800-378-4779
Mitoguazone dihydrochloride (MGBG)	Non-Hodgkin's Lymphoma refractory or relapsed	Ilex Compassionate Use Program	210-677-8000
Nevirapine (Viramune)	HIV Infection CD4 count $\leq$ 200/mm^3 Pediatrics only	Boerhringer-Ingelheim	800-595-5494
Nitazoxanide (NTZ)	*Cryptosporidium*	Unimed Pharmaceuticals Compassionate Use Protocol	800-864-6330
Sparfloxacin (Cinarcid)	Multidrug resistant TB	Rhone-Poulenc Rorer Compassionate Use Protocol	610-454-5467
Spiramycin	Chronic diarrhea caused by *Cryptosporidium*	Rhone-Poulenc Rorer Compassionate Use Protocol	800-727-6737
Thalidomide (Synovir)	Wasting syndrome Apthous ulcers	Celegen Celegen Emergency Treatment IND	800-253-1596 908-805-3914
VIRACEPT (nelfinavir)	HIV infection CD4 count < 100mm^3	Agouron Pharmaceuticals	800-621-7111

California AIDS Drug Assistance Program

The California AIDS Drug Assistance Program (ADAP) was established to provide drugs to individuals who otherwise could not afford them. Individuals are eligible for ADAP if they (1) have an adjusted gross income below $50,000 per year, (2) have a valid prescription from a California-licensed physician, and (3) the drugs they need are not covered by Medi-Cal or other third-party payer. An individual is subject to a co-payment if his/her annual adjusted gross income is between 400% of poverty level and $50,000. Individuals with an annual gross income below 400% of poverty level receive the drugs free of charge.

For more information about ADAP call the California Office of AIDS at **916-327-6784**. County and local offices in California are listed on the next page. Other States have similar programs.

California AIDS Drug Assistance Program - Covered Drugs

Common Name	Other Names	Used for
3TC	Lamivudine, Epivir	antiretroviral
AZT	ZDV, Retrovir, zidovudine	antiretroviral
Acyclovir	Zovirax	antiviral
Amphotericin B	Fungizone	antifungal
Atovaquone	Mepron	antibacterial
Azithromycin	Zithromax	antibacterial
Bleomycin sulfate	Bleonoxane	chemotherapy
Clarithromycin	Biaxin	antibacterial
Clindamycin	Cleocin	antibacterial
Clofazimine	Lamprene	antimycobacterial
Dapsone		antibacterial
d4T	Zerit, stavudine	antiretroviral
ddC	Zalcitabine, Hivid	antiretroviral
ddI	didanosine, Videx	antiretroviral
Doxorubicin	Adriamycin	chemotherapy
Dronabinol	Marinol	appetite stimulant
Erythropoietin	EPO, Epres, EPOGEN, Procrit	red blood cell stimulator
Ethambutol	Myambutol	antimycobacterial
Fluconazole	Diflucan	antifungal
Flucytosine	5FC	chemotherapy
Foscarnet	Foscavir	antiviral
G-CSF	Filgrastim, Neupogen	white blood cell stimulator
Ganciclovir, IV	DHPG, Cytovene, Ganciclovir	antiviral
Indinavir	Crixivan	antiretroviral, protease inhibitor
Invirase	Saquinavir	antiretroviral, protease inhibitor
Interferon, alpha	IFN, alpha IFN, Wellferon, Roferon-A, Intron-a, Interferon-alpha	immune modulator
Itraconazole	Sporanox	antifungal
Ketoconazole	Nizoral	antifungal
Leucovorin	Wellcovorin, Folinic acid	white blood cell protector
Megace	Megestrol acetate	appetite stimulant
Methotrexate	MTX, Reumatrex	chemotherapy
Mycelex	Clotrimazole	antifungal
Nystatin	Mycostatin	antifungal
Paromomycin	Humatin	antiparasitic
Pentamidine, aerosolized	Nebupent, Pentaire, Aeropent	antiparasitic (PCP)
Prednisone	Deltasone, Prednicen-M, Sterapred	steroid
Pyrimethamine	Daraprim	antibacterial
Rifabutin	Mycobutin	antimycobacterial
Ritonavir	Norvir	antiretroviral, protease inhibitor
Sulfadiazine	Microsulfon	antibacterial
Trimethoprim	Trimpex, Proloprim	antibacterial
Trimethoprim-Sulfamethoxazole	Bactrim, TMP-SMX, Septra	antibacterial
Trimetrexate glucuronate	NeuTrexin	antibacterial
Vinblastine	Velban	chemotherapy
Vincristine	Oncovin, Vincasar	chemotherapy

California AIDS Drug Assistance Program

County and Local Contacts for AIDS Drug Assistance Program in California

Alameda County Health Dept.
(510) 271-4230

City of Berkeley
(510) 644-6022

Butte County
(916) 895-0462

Contra Costa County
(510) 313-6602

Del Norte County
(707) 464-3191

El Dorado County
(916) 573-3155

Fresno County
(209) 445-3434

Glenn County
(916) 934-6588

Humboldt County
(707) 441-2045

Imperial County
(619) 339-4448

Kern County
(805) 861-3644, x366

Kings County
(209) 584-1401, x4520 or
(209) 582-3211, x4520

Lake County
(707) 263-2241

Lassen County
(916) 251-8183

Long Beach
(310) 570-4330

Los Angeles County
(213) 351-8084

Madera County
(209) 675-7627

Marin County
(415) 499-3624

Mendocino County
(707) 463-4573

Merced County
(209) 385-7700 x6170

Monterey County
(408) 759-7272 (NIDO Clinic)
(408) 394-4747 (Seaside)
(408) 772-8200 (Salinas)

Napa County
(707) 253-4570

Nevada County
(916) 477-5551

Orange County
(714) 834-8175 or
(714) 834-8241

City of Pasadena
(818) 405-4391

Placer County
(916) 889-7175

Plumas County
(916) 283-6330

Riverside County MIA Program
(909) 358-6453

Sacramento County
(916) 732-9183

San Benito County -- No ADAP
Clients should be referred to
Monterey County ADAP Program

San Bernardino County
(909) 383-3036 or
(909) 386-8112

San Diego County
(619) 236-2479

San Francisco County
(415) 554-9043

San Joaquin County
(209) 468-3839

San Luis Obispo County
(805) 781-3660

San Mateo County
(415) 573-2188

Santa Barbara County
(805) 681-5303

Santa Clara County
(408) 299-6150

Santa Cruz County
(408) 454-4574

Shasta County
(916) 247-3338

Siskiyou County
(916) 842-8237

Solano County
(707) 553-5555

Sonoma County
(707) 524-7402

Stanislaus County
(209) 525-7336

Tehama County
(916) 527-6824

Tulare County
(209) 685-2535

Tuolumne County
(209) 533-7400, x7412

Patient Assistance Programs

Some pharmaceutical companies have programs that provide free or lower cost medications to patients who could not otherwise pay for them. Each program has specific requirements about who is eligible and what kind of financial help is available. If you need help paying for any of the drugs listed below, talk to your doctor. He or she will need to call the coordinators of the appropriate program(s) and give them information about your financial status and prescription drug needs.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
3TC (Lamivudine, Epivir)	HIV Infection	GlaxoWellcome Co. HIV Patient Assistance Program	800-513-3028
Acyclovir (Zovirax)	Herpes simplex, Herpes zoster	GlaxoWellcome Co. HIV Patient Assistance Program	800-513-3028
Alpha Interferon-2A recombinant (Roferon-A)	Kaposi's Sarcoma (>200 T-cells) anogenital neoplasms	Hoffmann-LaRoche, Inc. Oncoline (Reimbursement assistance and literature search) Indigent Patient Program	 800-443-6676 800-285-4484
Alpha Interferon-2B recombinant (Intron A)	Kaposi's Sarcoma anogenital neoplasms	Schering-Plough Corp. Commitment to Care	800-521-7157
Amphotericin B Lipid Complex (ABELCET)	Life threatening fungal infections	Liposome Co. Indigent Patient Program	 800-335-5476
Atovaquone (Mepron)	PCP treatment	GlaxoWellcome Co. HIV Patient Assistance Program	800-513-3028
AZT (zidovudine, Retrovir)	HIV infection	GlaxoWellcome Co. HIV Patient Assistance Program	800-513-3028
Cimetidine (Tagamet)	Ulcers	SmithKline Beecham, Access To Care	800-546-0420
Ciprofloxacin (Cipro)	Bacterial Infections	Bayer Indigent Patient Program	800-998-9180
Clarithromycin (Biaxin)	MAC	Abbott Laboratories Physician calls only	800-688-9118
Clindamycin	PCP treatment	Upjohn Co. Patient Assistance Program	800-242-7014
Clofazimine	MAC Treatment/Prevention	Ciba Pharmaceuticals Patient Assistance Program	800-257-3273
Compazine	Nausea	SmithKline Beecham Access To Care	800-546-0420
Crixivan (Indinavir)	HIV Infection	Merck and Co.	800-850-3430
ddC (zalcitabine, HIVID)	HIV infection	Hoffman-La Roche, Inc. Oncoline	800-285-4484
ddI (didanosine, Videx)	HIV Infection	Bristol-Myers Squibb Videx Assistance Program	800-426-7644
d4T (stavudine, Zerit)	HIV Infection	Bristol-Myers Squibb Patient Assistance Program	800-426-7644
DOXIL (liposomal doxorubicin)	Kaposi's Sarcoma	SEQUUS Pharmaceuticals Patient Assistance Program	800-375-1658
Dronabinol (Marinol)	Appetite stimulant	Roxane Laboratories Patient Assistance Program	800-274-8651
EPO (erythropoietin, Procrit)	AZT-related anemia	Ortho Biotech Procrit Financial Assistance Program	800-553-3851

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Ethambutol (Myambutol)	TB treatment, MAC treatment	Wyatt-Aerst Patient Assistance Program (physician calls only)	800-568-9938
Fluconazole (Diflucan)	Fungal infections	Pfizer Inc. Diflucan patient assistance program	800-869-9979
Foscarnet (Foscavir)	CMV disease, acyclovir-resistant HSV	Astra Pharmaceuticals Foscavir Assistance	800-488-3247
Ganciclovir (Cytovene)	CMV disease	Roche-Syntex Laboratories Provisional Assistance Programs	800-444-4200
Ganciclovir implant (Vitrasert)	CMV retinitis	Chiron Vision Patient Assistance Program	800-843-1137
G-CSF (Neupogen)	AZT-related neutropenia	Amgen, Inc.	800-272-9376
GM-CSF (Leukine)	AZT-related neutropenia	Immunex Corporation (Physician calls only)	800-334-6273
Human Growth Hormone rHGH Serostim	HIV Wasting Syndrome	Serono Laboratories	800-714-2437
Itraconazole (Sporanox)	Histoplasmosis, Fungal infections	Janssen Pharmaceutica Patient Assistance Program	800-544-2987
Ketoconazole (Nizoral)	Fungal infections	Janssen Pharmaceutica Patient Assistance Program	800-554-2987
Megestrol Acetate (Megace)	HIV-related Wasting	Bristol-Myers Squibb Patient Assistance Program	800-426-7644
Mycelex	Oral Candidiasis (thrush)	Bayer Indigent Patient Program	800-998-9180
Octreotide Acetate (Sandostatin)	Wasting	Sandoz Pharmaceuticals Corp. Indigent Patient Program	800-447-6673
Pentamidine (Nebupent)	PCP Prophylaxis	Fujisawa, USA, Inc.	800-888-7704, x8607
Pentoxifylline (Trental)	HIV Infection, KS, Dementia	Hoechst Marion Roussel Inc. Indigent Patient Program	800-552-3656
Pyrimethamine (Daraprim)	Toxoplasmosis	GlaxoWellcome Co. HIV Patient Assistance Program	800-513-3028
Rifabutin (Mycobutin)	MAC	Pharmacia Upjohn Inc.	800-366-5570
Ritonavir (Norvir)	HIV Infection	Abbott Labs Temporary Assistance Program (Physicians only)	800-659-9050
Saquinavir (Invirase)	HIV Infection	Hoffmann-LaRoche, Inc. Patient Assistance Program	800-285-4484
Streptomycin	TB treatment	Pfizer Inc., Patient Assistant Program	800-254-4445
Trimethoprim/sulfamethoxazole (TMP-SMX, Septra, Bactrim)	PCP prophylaxis Acute PCP	GlaxoWellcome Co. HIV Patient Assistance Program (Septra) Hoffmann-La Roche, Inc. Reimbursement Assistance (Bactrim)	800-513-3028 800-285-4484
Trimetrexate (Neutrexin)	PCP, Toxoplasmosis	US Bioscience Patient assistance program	800-887-2467
WinRho SD	HIV-related ITP	Univax Biologics / Physician calls only	800-789-2099

Common Questions about Clinical Trials

What is a clinical trial?

A new drug goes through many tests in the lab before people take it. If the results are good, the drug is tested in small groups of people. When people take a new drug as part of a study, it is called a clinical trial.

The results of a clinical trial are very important. They tell us about the safety of the drug when people take it. They also tell us if the drug helps people get better.

Why should I join? What do I get out of this?

Here are some of the reasons to join a clinical trial:

- The treatment being tested may work for you.
- Clinical trials may be the only way to get a promising new drug.
- Drugs taken as part of a clinical trial are usually free. (Even if a drug you want to take is available on the "under ground," or by prescription, you may not be able to afford it).
- You can help speed the development of new treatments for HIV.

Will I be used as a "guinea pig"?

Before you join a clinical trial, you should understand what will happen during the study and what the researchers hope to learn. When you join a clinical trial, you volunteer of your own free will. Even though you signed a consent form, you have the right to quit at any time.

In most cases, you join a clinical trial because you already have a disease and you think the drug being tested may help you. Sometimes, you may join a clinical trial while you are still healthy, in the hope that the treatment may prevent you from getting sick.

What if the drug makes me sicker?

The researchers who design the trials always plan what to do if a volunteer gets ill from the drug they are studying. If the drug makes you sicker, you may have to take a lower dose, or stop taking the drug completely. In some trials, you might be switched to another drug. You should keep in close contact with your doctor as well as the researchers so they can treat any side effects as soon as possible.

Will I have to take a placebo ("sugar pill")?

Placebos are usually used only when no effective treatment is known. In these cases a "placebo-controlled" study is the only reliable way to find out if a drug works. Some patients are asked to take placebos so researchers can learn whether changes in health are caused by the drug, or would have happened without treatment.

Patients who take placebos get the same medical attention as people who get the study drug. Usually, all patients in the study are offered the active drug if it is shown to be safe and effective.

How can I tell which trial might be good for me?

The more you know about your own health status and about HIV disease, the easier it will be for you to make decisions about what trials may be good for you. You should always talk to your doctor or health care provider to get their opinions, too. We list contact names and numbers for the trials included in this directory so you or your doctor can get more information about trials you are interested in.

What are my rights as a patient?

The people involved in your care must treat you with consideration and respect. You have the right to:

- be told all the important details about your care
- ask questions and have them answered
- say no to any test, procedure or medication
- go to another health care provider to get more information
- know the names of anyone you talk to
- read your medical records with your health care provider
- make your own decisions about your health care
- know that your medical records will be kept confidential

What are my responsibilities as a patient?

The researchers have a right to expect certain things from you, too. As a patient, you have the responsibility to:

- be honest about your medical history and anything in your lifestyle which may affect your health
- follow instructions and take the study drug(s) as requested
- keep appointments or re-schedule them in advance
- report any changes in your health
- be sure you understand the facts before you make a complaint

What is informed consent?

Researchers are required by law to give you all the facts about a study before you join. This information must be explained in a way that you can understand. Before you join a study, you will be asked to read and sign a consent form. This is called giving ***informed consent***.

When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join. The consent form is not a contract. You do not give up any rights if you sign the consent form. You can leave the study at any time.

What should I know before I sign the consent form?

Before you sign the consent form, you should know:

- the reasons for using the experimental treatment
- the risks and benefits of taking part in the study
- if there are any extra costs, doctor visits, lab tests, etc.
- what drugs you will have to take

Are there any other questions I should ask before I sign the consent form?

Before you decide to join a trial, you may want to know:

- How will information about me be handled to protect my privacy?
- Can I take the drug after the trial is over? Will I have to pay for it?
- If I get sick or develop health problems while on the trial, will I be taken off the trial?
- How can I find out the results of the trial?
- Are there other studies of this drug I should know about?
- Do I have to use birth control? If so, what kind? If I become pregnant will I have to leave the study?

What should I do If I don't understand something?

Do not sign the consent form until you understand everything in it. Keep asking questions. The staff should be able to answer most of them. However, there may not be enough information about certain drugs to answer some questions.

Why do some studies pay people to participate?

Some research studies pay people who volunteer to participate in them. Usually, studies only pay when there is no expected medical benefit to participants, such as when a new drug is being tested for only a short amount of time. Sometimes studies pay when they ask a lot of time and energy from participants, such as overnight stays in the hospital, or long surveys about personal issues.

Some researchers feel that the offer of money is not always ethical because it may tempt some people to take risks that they would not take otherwise. Ask and understand why the study is paying participants before you decide whether to join. Keep in mind that studies that pay usually do not pay until the study is over.

When studies do not pay, it is because the potential benefit of the study is felt to be enough compensation for the effort and risk of participating in it. If a study gives you free medication, check-ups, lab tests and helps you to be healthier by curing or preventing disease, then you *do* get something out of your participation.

Getting more information about specific studies

If you want to find out more about a specific clinical trial, call the person listed under "Location" for that trial. This is usually a research nurse or study coordinator. S/he will ask you some questions about your health to find out if you fit the entry criteria for the trial. It is a good idea to have a copy of your most recent laboratory tests, such as blood tests and T-cell counts, when you call.

Finding out if you're eligible: The screening visit

If the research nurse thinks you may be eligible, s/he will ask you to come in for a "screening" visit. At this visit, someone will explain the study to you, and you will give them more information about your health and your medical history. You may also have a brief physical exam and have some blood tests done.

Giving "informed consent"

If you meet all the entry criteria you will be asked to sign a consent form. When you sign the consent form it means that you have been given all the information about the study, and that you agree to participate.

The first study visit

After you have signed the consent form, you can join the study during a "baseline" visit—the first official visit of the study. A lot of information is collected during the baseline visit, so it may take longer than your regular office visit.

Followup visits

If you are taking a new drug, you will probably be asked to come back to the office for another visit in 1 - 2 weeks. This is to watch for any side effects of the drug that you may be experiencing. If everything seems to be all right, you will be asked to come back for regular followup visits. Frequency of visits may vary from daily to every few months, depending upon the study.

Keeping in touch

It is important to come to each study visit, and to let the researchers know how you are doing. It's also important to keep seeing your regular health care provider. Everyone is interested in protecting your health and safety when you are in a clinical trial, so it is important to stay in touch.

There are a number of misunderstandings about women and clinical trials. Here are the facts about some of the most common misunderstandings.

Can women with HIV join clinical trials?

Yes. Every clinical trial has requirements about who can join. If a woman meets these requirements, she can join. Most clinical trials are open to both women and men.

Women often don't get enough information about clinical trials and think that they cannot join simply because they are women.

Check the index of this Directory for studies that are open only to women, but remember that women may also join nearly all of the other studies listed.

Are there special rules about birth control and pregnancy?

Yes. In many studies, women must agree to use birth control if they have sex with men. Pregnant or nursing women usually can't join a trial of an untested drug because it is not known if the drug might harm the baby. However, there are now a few studies for pregnant women.

What happens if a woman becomes pregnant while in a trial?

A woman should know the rules about pregnancy before she joins a trial. Different trials have different rules about whether a woman can continue in the trial if she becomes pregnant.

Some women think they must have an abortion if they become pregnant while in a study. This is not true. Every woman always has the right to make her own decisions about pregnancy. No one can force you to have an abortion. However, if you choose to have the baby, it may affect your continued participation in the trial.

If you become pregnant, you may want to talk to the contact people for the studies for children listed in this guide (pages 70-80). These people are usually experts in pregnancy and women with HIV and can give you the most current information.

Services for women with HIV -- Los Angeles Area

There are too many programs and services for women in the Los Angeles area to list here. To receive a full listing, contact AIDS Project Los Angeles for a free copy of their guide to LA resources.

AIDS Project LA (213) 993-1459 (English)

(213) 993-1483 (Spanish)

Services for women with HIV -- San Diego Area

Being Alive has programs for women and children, including treatment education and advocacy.

San Diego: (619) 291-1400 or 1-800-606-2224

Services for women with HIV -- Northern California

WORLD (Women Organized to Respond to Life-Threatening Diseases). These women publish a newsletter with treatment information, and organize classes to teach themselves about HIV, including information on clinical trials. They can also offer referrals to services in the Bay Area.

You may contact WORLD at (510) 658-6930.

Check the Resources section on page 107 for more resources of interest to women.

Most trials for adults do not allow children under the age of 13 to join. But there are clinical trials designed especially for children from birth to age 13 or older. Children's research is done by doctors and nurses who are experts on children's bodies and health.

Why are there trials for children only?

Children's bodies are different from adults' bodies, and HIV affects children differently than adults. For example, children get certain infections more frequently than adults, and never get some infections that adults get. It is important that your child see a doctor who knows about both HIV and children.

Because children's bodies are different from adults', a drug may work differently in children. Some drugs work very well in children and not at all in adults. A child usually needs a lower dose of a drug. Some drugs are too strong to give to children or have side effects that are worse for children than adults. Because of these differences, most researchers feel that it is better to test drugs separately in children.

Is it ethical to do research with children?

Some people think that it is never right to do research with children because children are too young to decide for themselves to take part in research. They feel it is not fair to put children at risk. Others feel that with AIDS and other life-threatening diseases that don't have a cure, the risk of the disease is greater than the risk of taking a drug that hasn't been thoroughly tested. Research may be the only chance to get certain drugs, and these drugs may be the only hope of getting better.

A child's parent or guardian must give written permission before a child can join a clinical trial. This permission is called ***"informed consent"***.

Where can I find out more about clinical trials for children with HIV?

This Guide lists trials for children at the end of the clinical trials section beginning on page 70.

You can call the contact people for the studies listed there—these people are usually medical experts on children with HIV and should be able to answer your questions.

What does "youth" mean?

People use the term "youth" differently. It can mean people from 13 to 18 years old, or 13 to 21 years old, or 13 to 26 years old. Other words used for youth are "adolescent" and "teen."

Why are youth treated differently in clinical trials?

Youth are different physically and emotionally from both children and adults. Healthcare and support programs for youth take these differences into account.

In which trials may youth participate?

Most clinical trials allow youth to join. Often people between ages 13 and 18 are eligible for both children's and adults' clinical trials. We list age restrictions for all the trials in this directory.

Do youth under 18 need permission to join a clinical trial?

Yes, minors (younger than 18 years old) need to get written permission from a parent or guardian to join a drug trial, even if they get medical care at a clinic without permission. There are people working to change the laws in this area, and they may be able to help you join a trial without your parents' permission in certain situations. See the "Common Questions" section of this Directory for an explanation of what it means to give ***"informed consent."***

Youth and Clinical Trials

Medical & Referral Services for Youth with HIV—Northern California

Bay Area Young Positives (BAY Positives)
Antigone Hodgkins, Executive Director
518 Waller Street
San Francisco, CA 94117
(415) 487-1616

BAY Positives is an education, support and advocacy organization by and for young people with HIV from the entire Bay Area.

Project AHEAD
Clark Moore, Director
1242 Market Street, 3rd Floor
San Francisco, CA 94102
(415) 487-5777
Project Ahead provides information to HIV+ youth and their providers about clinical trials.

Larkin Street Medical Clinic
1044 Larkin Street (at Sutter Street)
(415) 673-0911
Free medical and support services for homeless and runaway youth ages 12 to 23.

UCSF Teen Clinic
400 Parnassus, 2nd Floor, Room A270
(415) 476-8626 (Dave Knopf)
Full medical and support services.

San Francisco General Hospital
1001 Potrero Avenue (between 22nd and 23rd Streets)
Teen and Adolescent Clinic (under 18 years old)
(415) 206-8376

Kaiser Teenage Clinic
2350 Geary Boulevard, 1st Floor
(415) 202-2213
Medical and support services for youth who have Kaiser insurance or MediCal.

Medical & Referral Services for Youth with HIV—Southern California

Childrens Hospital LA
Risk Reduction Program
5000 Sunset Boulevard, 4th Floor, LA, CA 90027
(213)669-2390
Free health care and treatment ot young people with HIV between the ages of 12 and 24. Case management, psychosocial and nutritionsal education services also available.

High Risk Youth Program: (213) 669-2503
4650 Sunset Boulevard #2
Los Angeles, CA 90027
Medical services for homeless youth.
Department of Adolescent Medicine: (213) 660-2450
This department has several open or about to open studies designed especially for youth. Some of these are "natural history" studies that are trying to learn about young people with HIV and their situations and needs. Call and participate!

LA County USC Medical Center: 5P21 Clinic
1300 North Mission Rd., LA, CA 90033
(213) 343-8255
Adult, maternal and pediatric care and medical services.

Youth HIV Project
5000 Sunset Boulevard, 4th Floor, LA, 90027
(213) 669-2390
Free medical crae for HIV infected youth 12 to 20 years old, support groups, case management, health education.

Children's Hospital and Health Center
3020 Children's Way
San Diego, CA 92123
(619) 576-1700

Injection Drug Users and Clinical Trials

Injection drug users and people who use illegal street drugs, such as heroin, crack and speed, have often been left out of clinical trials. There are several reasons for this.

Street drugs can cause damage to the liver or kidneys. If your liver or kidneys are already damaged, taking a study drug might cause even more harm. Some trials have complicated rules that participants must follow. Researchers may think that if you use drugs you won't show up for your clinic visits, or won't take the study drugs as directed.

Most of the clinical trials in this directory ***do not*** exclude people just because they have used illegal drugs. If you are told you cannot join a clinical trial, ask the reason why. If you are (or were) an injection drug user, one of the following reasons may explain why you cannot join the trial.

Damaged liver or kidneys

Doctors can use certain laboratory tests to find out if your liver and kidneys are healthy. This is important, because you can have harmful side effects from the study drug if your liver or kidneys are damaged. These tests are usually done during the "screening" visit. If any of the tests are "outside normal limits," you may not be able to join the trial. This is done to protect your health.

Dangerous drug interactions

It can be very dangerous to mix some drugs, or to mix drugs and alcohol. Even mixing methadone with some study drugs can be dangerous. It is important to let your doctor and the researchers know ***every*** drug you are taking, to prevent harmful side effects.

Unable to comply with the "rules" of the study

Some trials have very complicated rules, and some people find it hard to follow them. That is why, if your doctor thinks you are "unreliable," you may not be able to join a clinical trial. If you do not take the study drug as directed, or frequently miss clinic appointments, it may be impossible to learn if the drug is working, or to prevent harmful side effects.

AIDS Community Research Consortium
1048 El Camino Real, Suite A
Redwood City, CA 94063
(415) 364-6563

AIDS Healthcare Foundation
1300 N. Vermont Ave., Suite 502A
Los Angeles, CA 90027
(213) 913-3953

AIDS Research Alliance
621-A North San Vicente Blvd.
West Hollywood, CA 90069
(310) 358-2429

Bay Area Perinatal AIDS Center (BAPAC)
1001 Potrero Avenue, Room 6D1
San Francisco, CA 94110
(415) 206-8919

Beer Medical Group
5901 West Olympic Boulevard, #420
Los Angeles, CA 90036
(213) 937-5151

California Clinical Trials Medical Group
8500 Wilshire Boulevard, 7th Floor
Beverly Hills, CA 90211
(310) 854-4949

California Infectious Disease Associates
2900 Whipple Ave., Suite 115
Redwood City, CA 94062
1-800-910-2432

California Partners Study
UCSF Dept. of OB/GYN
74 New Montgomery, Suite 400
San Francisco, CA 94105-3411
(800) 262-2430

Cedars-Sinai Medical Center
Division of Infectious Diseases
8700 Beverly Boulevard, #B-226
Los Angeles, CA 90048
(310) 855-3755

Center for Special Immunology - Irvine
100 Pacifica, Suite 100
Irvine, CA 92718
(714) 753-0670

Center for Special Immunology - San Diego
2918 Fifth Ave., Suite 300
San Diego, CA 92103-5910
(619) 291-1122

Children's Hospital of Los Angeles
4650 Sunset Boulevard MS 54
Los Angeles, CA 90027
(213) 668-2180

Children's Hospital, Oakland
747 - 52nd Street
Oakland, CA 94609
(510) 428-3337

Community Consortium
(See page 103 for a list of participating sites and providers)
3180 18th Street, #201
San Francisco, CA 94110
(415) 476-9554

Community Eye Medical Group - Brian G. Terry, MD
301 S. Fair Oaks Avenue, #104
Pasadena, CA 91105
(818) 287-2000

Davies Medical Center HIV Institute
Castro and Duboce
San Francisco, CA 94114
(415) 565-6660

Desert AIDS Project
750 S. Vella Rd.
Palm Springs, CA 92264
(619) 323-2118 ext. 235

Desert Hospital Comprehensive Cancer Center
1180 N. Indian Canyon, Suite E320
Palm Springs, CA 92262
(619) 416-4734

Clinical Trials Sites

East Bay AIDS Center
3031 Telegraph Avenue, Suite 235
Berkeley, CA 94705
(510) 204-1870

HIVCare, Saint Francis Memorial Hospital
900 Hyde Street
San Francisco, CA 94109
(415) 353-6215

Harbor-UCLA Medical Center
1124 W. Carson Blvd.
REI N-24
Torrance, CA 90502
(310) 222-3848

Immune Enhancement Project
3450 16th Street
San Francisco, CA 94114
(415) 252-8711

Jeffrey Goodman Special Care Clinic
1625 N. Schrader Blvd.
Los Angeles, CA 90028
(213) 993-7500

Kaiser San Francisco - HIV Research Unit
2590 Geary Boulevard
San Francisco, CA 94115
(415) 202-3480

King-Drew Medical Center
12021 South Wilmington Ave.
OASIS Clinic Los Angeles
Los Angeles, CA 90059
(310) 668-4213

Kraus Medical Partners
5901 W. Olympic Boulevard, Suite 310
Los Angeles, CA 90036
(213) 930-2324

LAC-USC Medical Center
1300 North Mission Rd.
Los Angeles, CA 90033
(213) 343-8288

LAC-USC Medical Center - Maternal Child Program
1640 Marengo Avenue
HRA Bldg., 3rd Floor
Los Angeles, CA 90033
(213) 226-5068

LAC-USC Medical Center - Norris Cancer Hospital
1441 Eastlake Ave., Room 3016 MS 34
Los Angeles, CA 90033
(213) 226-4578

Marcus Conant, MD Clinical Research
350 Parnassus Avenue, Suite 808
San Francisco, CA 94117
(415) 661-2613

Marin County Specialty Clinic
250 Bon Air Road
Greenbrae, CA 94904
(415) 499-7377

Pacific Oaks Research Group
448 North Bedford Drive
Beverly Hills, CA 90210
(310) 275-9346

Peachwood Medical Center
275 West Herndon
Clovis, CA 93612
(209) 324-6257

Quan Yin Healing Arts Center
1748 Market Street
San Francisco, CA 94114
(415) 861-4964

Quest Clinical Research, San Francisco
2300 Sutter Street, Suite 202
San Francisco, CA 94115
(415) 353-0800

Retina-Vitreous Group-David Boyer, MD
8641 Wilshire Blvd., Suite 210
Beverly Hills, CA 90211
(310) 854-6201

SFGH Dermatology
SFGH 4M70
San Francisco, CA 94110
(415) 206-8680

San Francisco General Hospital GI Clinic
1001 Potrero Avenue, Room 3C
San Francisco, CA 94110
(415) 206-8824

San Mateo County AIDS Program
3700 Edison Street
San Mateo, CA 94403
(415) 573-2588, 415-573-2385

Santa Clara Valley Medical Center
Early Intervention Project
976 Lenzen Avenue
San Jose, CA 95126
(408) 885-4316

Shared Medical Research Foundation
5620 Wilbur Avenue
Tarzana, CA 91356
(818) 345-2172

Stanford University Medical Center
Center for AIDS Research
300 Pasteur Drive, Room S-156
Stanford, CA 94305
(415) 723-6231

Tower Infectious Diseases
8631 West Third Street, Suite 1015E
Los Angeles, CA 90048
(310) 358-2300

UC Davis Cancer Center
4501 'X' St., G-126
Sacramento, CA 95817
(916) 734-3604

UC Davis Medical Center
Division of General Medicine
2221 Stockton Boulevard, Room 3107
Sacramento, CA 95817
(916) 734-7004

UC Irvine College of Medicine
19722 MacArthur Boulevard
Irvine, CA 92715
(714) 824-6255

UC Irvine Medical Center
101 City Drive South, Building 53
Route 81
Orange, CA 92668
(714) 456-7612

UCLA CARE Center
18033 Le Conte Avenue
BH-412 CHS
Los Angeles, CA 90095
(310) 206-6414

UCLA Medical Center - Pediatrics
10833 Le Conte Avenue
Los Angeles, CA 90095
(310) 206-6369

UCSD Treatment Center
2760 - 5th Avenue
San Diego, CA 92103-6325
(619) 543-8080, ext. 238

UCSD Treatment Center - Pediatrics
2760 - 5th Avenue
San Diego, CA 92103-6325
(619) 543-8080 ext. 261

UCSF AIDS Clinic
400 Parnassus Avenue, 5th Floor
San Francisco, CA 94143
(415) 476-3226

UCSF AIDS Program at SFGH / ACTG
995 Potrero Avenue, Building 80, Ward 84
San Francisco, CA 94110
(415) 476-9296, ext. 354

UCSF AIDS Program at SFGH/ICTG
995 Potrero Avenue, Building 80, Ward 87
San Francisco, CA 94110
(415) 476-9296, ext. 310

UCSF Infectious Diseases Research
505 Parnassus Ave, Room AC30B
UCSF Box #0919
San Francisco, CA 94143
(415) 476-2308

UCSF / Mt. Zion AIDS Oncology Practice
2356 Sutter Street, 5th Floor, Pavillion
San Francisco, CA 94115
(415)885-7252

UCSF Pediatric Immunology Program
505 Parnassus Avenue, Room M679
San Francisco, CA 94143
(415) 476-9373

UCSF/SFGH Dermatology
400 Parnassus, 3rd Floor
San Francisco, CA 94143
(415) 476-9219

UCSF / Veterans Administration Dept. of Psychiatry
4150 Clement Street
Psych. Services, 116R
San Francisco, CA 94121
(415) 476-7650

Veterans Administration Medical Center, San Francisco
4150 Clement Street, Room 111 W
San Francisco, CA 94121
(415) 221-4810, ext. 3763

ViRx, Inc.
1375 Sutter St., Suite 407
San Francisco, CA 94109
(415) 353-5623

Community Consortium Sites and Providers

The Community Consortium conducts clinical trials at over a dozen sites in the San Francisco Bay Area. Health care providers who are participating in the Consortium's clinical trials program are listed below. If you are interested in enrolling in a Consortium clinical trial and your health care provideris listed here, you can discuss enrollment during your next office visit.

San Francisco — Private Practices
Jon Kaiser, MD
Martin Mass, MD
Kenneth Mills, MD
William Owen, MD
Carl Stein, PA

San Francisco Castro-Mission Health Center
Nilda Alverio, MD
Jane Bailowitz, MD
Deborah Brown, MD
Toby Dyner, MD
Walter Krampf, MD
Lawrence Price, MD
Fred Strauss, MD
Ron Underwood, MD

Kaiser Permanente AIDS Research Unit — San Francisco
Eric Dummel, MD
Jeffrey Fessel, MD
George Matula, MD

Mission Neighborhood Health Center — San Francisco
Colleen Foy, MD
Ricardo Alvarez, MD
Steve Leiner, NP
Richard Dolbec, MD

San Francisco General Hospital AIDS Outpatient Clinic (Ward 86)
Donald Abrams, MD
Gary Carr, NP
Molly Cooke, MD
Steven Deeks, MD
Stephen Follansbee, MD
Sandra Hernandez, MD
Mark Jacobson, MD
Dennis James, PA
James Kahn, MD
Jill Legg, MD
Catherine Lyons, NP
J. B. Molaghan, NP

San Francisco General Hospital AIDS Outpatient Clinic (Ward 86), continued
Edward Murphy, MD
Meg Newman, MD
Herminia Palacio, MD
Laura Strauss, PA
Daniel Wlodarczyk, MD

Veterans Administration Hospital, San Francisco
Harry Lampiris, MD

East Bay — Private Practices
Robert Scott, MD
Don Sally, PA-C

East Bay AIDS Center (Alta Bates Herrick Medical Center), Berkeley
Claire Borkert, MD
Carol Brosgart, MD
Steve O'Brien, MD

Highland General Hospital Adult Immunology Clinic, Oakland
Kathleen Clanon, MD
Howard Edelstein, MD
Jeff Frank, MD
Deborah Royal, NP
Beth Schweitzer, MD
Lisha Wilson, MD

North Bay — Private Practice
Milton Estes, MD
Grace Dammann, MD
Debbie Jernberg, FNP

Access Project

1-800-734-7104
e-mail: AIDSTreatD@AOL.com
Internet: http://health.nyam.org:8000/public_html.network.index.html
A national clearinghouse for information about treatment access. For information about what drugs and treatments are available through federal, state or pharmaceutical-industry-sponsored programs, including:
- Medicaid and AIDS Drug Assistance Programs
- Patient Assistance /Expanded Access Programs
- Information about particular treatments.

AIDS Treatment News

Newsletter reporting on treatments for HIV / AIDS and public policy issues. Published twice a month. Subscription fee (available free or at low cost for people with limited income). Call for information. Highly respected.
Phone: (800) TREAT-1-2
(415) 255-0588
Address: P.O. Box 411256, San Francisco, CA 94141

AIDS Clinical Trials Information Service

Free national hotline, in English and Spanish, for information about AIDS Clinical Trials. Hours are Monday through Friday, 6:00am - 4:00pm (California time).
Phone: 1-800-874-2572 (1-800-TRIALS-A)

Gay Men's Health Crisis Treatment Issues

Reputable newsletter of experimental AIDS therapies published by Gay Men's Health Crisis in New York. Subscription charge.
GMHC Medical Information
129 West 20th Street
New York, NY 10011
FAX: 212-337-3656
Internet: http://www.gmhc.org

Medical Alert

Newsletter of the National Association of People with AIDS
1413 K Street, NW
Washington, DC 20005

National HIV/AIDS Treatment Hotline

1-800-448-0440
For federally approved treatment guidelines and information. Calls accepted from people with HIV, families, friends, health care providers. All calls are confidential.

Project Inform

Sponsors town meetings for information about and discussion of treatment twice a month. Information sheets and newsletter about available experimental drugs in treating AIDS, ARC, and HIV infection. Researches and disseminates information about where and how to obtain experimental drugs, current pricing, and what is known about dosage and clinical trials. California Hot-line. Free, donations for information sheets and newsletters accepted. Knowledgeable staff.
Phone: (800) 334-7422 (California only)
(415) 558-9051
Address: 1965 Market Street, San Francisco, CA 94103
Internet: http://www.projinf.org

Trials Search

A free computerized clinical trials matching service that provides people with HIV with personalized lists of studies for which they may qualify based on their medical history. Database covers all open trials in California. To receive a report, complete the Trials Search questionnaire (found in this Guide or by calling the number below), or conduct your own search at the Trials Search site on the World Wide Web. Trials Search is a service provided by the Community Consortium.
Phone: (800) 492-5777
(415) 476-5777
Address: 3180 18th Street, #201, SF, CA 94110
Internet: http://hivinsite.ucsf.edu/tsearch

WORLD

(Women Organized to Respond to Life-Threatening Diseases)

Newsletter contains updates about clinical trials and treatment information of interest to women. Organization sponsors "HIV-University" (HIV-U) to teach women infected with HIV about all aspects of HIV disease.
Phone: (510) 658-6930
Address: 3948 Webster Street, Oakland, CA 94609

Northern California Treatment Education and Advocacy Resources

ACT-UP Golden Gate Chapter / Treatment Issues Committee
Political action group. Committee works to reform treatment and drug development priorities and revolutionize the health care delivery system. Many members are very HIV knowledgeable.
Phone: (415) 252-9200 Information & announcements
(415) 252-9275 Office
Address: 519 Castro Street San Francisco, CA 94114

Bay Area Perinatal AIDS Center (BAPAC)
Center at San Francisco General Hospital that studies transmission of AIDS from pregnant women to their unborn children. Good source of information about women with HIV/AIDS and pregnancy.
Phone: (415) 206-8919
Address: 1001 Potrero Ave., Room 6D4, SF, CA 94110

Brother's Network
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to African-American gay, bisexual and transgender communities.
Phone: (415) 356-8140
Address: 973 Market Street, #650 SF, CA 94103

Healing Alternatives Foundation
"Buyers Club" for products aimed at improving the health of HIV positive people and people with AIDS, including vitamins, minerals, herbals, nutritional supplements, experimental substances, foreign products and more. Good resource and information library to encourage client participation in their health care program. Library is free, Buyers Club costs $1.00 to join. Open 12:00 to 6:00 pm, Tuesday through Friday; 12:00 to 5:00pm Saturday.
Phone: (415) 626-2316
Address: 1748 Market Street #205, SF, CA 94102

Living Well Project
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Asian-American and Pacific Islander communities. English, Cantonese, Vietnamese, Mandarin, Tagalog and Khmer spoken.
Phone: (415) 575-3939
Address: 1841 Market Street, SF, CA 94103

Mission Neighborhood Health Center, La Clínica Esperanza
General medical care, clinical trials and social services for the Latino/a community. Bilingual (Spanish / English) staff.
Phone: (415) 431-3212
Address: 240 Shotwell Street, San Francisco, CA 94110

Native American AIDS Project
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to American Indian community.
Phone: (415) 522-2460
Address: 1540 Market Street, #425, SF, CA 94102

Options Project, UCSF AIDS Program
Identifies individuals with primary HIV infection and provides those individuals with clinical care. Develops effective treatment programs for HIV infections of less then seven months duration and to see if current treatment plans are capable of eradicating HIV infection when given early in the course of disease. Provides ways of referring high risk individuals into behavioral intervention programs in order to prevent infection.
Phone: (415) 476-9296 ext. 119
Address: SFGH Bldg. 80, Ward 84, SF, CA 94110

Proyecto ContraSIDA por Vida
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Latino communities, especially gay, lesbian, bisexual and transgender HIV positive people. Spanish and English spoken.
Phone: (415) 575-1642
Address: 2973 16th St., San Francisco, CA 94110

San Francisco AIDS Foundation
Information and referrals to AIDS service organizations for people who need emotional or practical support. Spanish and Tagalog speaking staff. Publishes **BETA, the Bulletin of Experimental Treatments for AIDS**. **BETA** is published four times a year and has very up to date information on various aspects of HIV infection.
Phone: 1-800-FOR-AIDS (English, Spanish, Filipino)
(415) 863-2437 (**BETA** subscription info.)
(800) 327-9893 (**BETA**, outside SF)
Address: 10 United Nations Plaza, SF, CA 94102-6182

Los Angeles Area Treatment Education and Advocacy Resources

AIDS Project Los Angeles
1313 N. Vine St.
Los Angeles, CA 90028
(213) 993-1459
(213) 993-1483 (Spanish)
Publishes *HIV LA*, an extensive directory of HIV resources in LA and *Positive Living*, a monthly newsletter that includes timely treatment and clinical trial updates Call for free copies or subscriptions.

AIDS Service Center
126 W. Del Mar Blvd.
Pasadena, CA 91105
(818) 796-5633

AIDS Project Long Beach
2017 E. 4th St.
Long Beach, CA 90814
(310) 434-4455

L. A. Shanti
1616 N. La Brea Ave.
Hollywood, CA 90028
(213) 962-8197

WomensLink
4410 Sepulveda Blvd.
Culver City, CA 90230
(310) 313-5139

Bienestar Latino AIDS Project
1169 N. Vermont Ave.
Los Angeles, CA 90029
(213) 660-9680

Asian Pacific AIDS Intervention Team
1313 W. 8th St., Suite 224
Los Angeles, CA 90017
(213) 353-6055

AIDS Prevention Team
1219 S. La Brea Ave.
Los Angeles, CA 90019
(213) 964-7820

Selected San Diego Area Resources

AIDS Foundation San Diego
140 Arbor Drive
San Diego, CA 92103
Hotline: (619) 686-5000

Being Alive-San Diego
3960 Park Boulevard
San Diego, CA 92103
(619) 291-1400
Newsletter, support groups, counseling, housing

Being Alive Center for Women and Children
3265 5th Avenue
San Diego, CA 92103
(619) 298-5099
Direct services, advocacy and education

San Diego County Department of Health and Human Services / Office of AIDS Coordination
P.O. Box 85222
Administrative Center, Room 208
San Diego, CA 92186
(619) 515-6699

UCSD Medical Center
AIDS Testing and Treatment Center
2760 Fifth Avenue, Suite 30
San Diego, CA 92103
(619) 543-8080

Hemophilia Association
P.O. Box 23099
San Diego, CA 92193
(619) 560-8373

San Diego Health Alliance, HIV/AIDS Office
234 North Magnolia Avenue
El Cajon, CA 92020
(619) 579-8373

Selected Medical Abbreviations:

< :	less than
> :	greater than
≤ :	less than or equal to
≥ :	greater than or equal to
qd:	daily
tiw:	three times a day
bid:	twice a day
PO:	by mouth
SQ:	subcutaneous (injected under the skin)
IV:	intravenous (injected in a vein)
IM:	intramuscular (injected in a muscle)
mg.:	milligrams
ml.:	milliliters
mm.:	millimeters

Acquired Immunodeficiency Syndrome (AIDS): failure of the immune system believed to be caused by infection with the human immunodeficiency virus (HIV). The virus infects the body's cells that are essential to the proper functioning of the immune system.

Adjuvant: any substance that enhances the immune-stimulating properties of an antigen or the pharmacologic effect of a drug

Adverse reaction ("side effect"): toxic reaction to a substance. Common adverse reactions include rash, headaches, nausea, vomiting and drowsiness; and can be as severe as anemia, seizures and liver or kidney failure.

AIDS Dementia Complex (ADC): a degenerative neurological condition, generally attributed to HIV disease, with a wide variety of clinical presentations including loss of coordination, mood swings and loss of inhibitions, and widespread cognitive deficit.

Anaphylactic Shock: a life-threatening allergic reaction characterized by a swelling of body tissues (including the throat) and a sudden decline in blood pressure

Antibacterial: a substance which stops the growth of bacteria.

Antibiotic: a substance which kills or inhibits the growth of disease causing organisms, such as bacteria and fungi. For example, penicillin for some bacteria, amphotericin B or nystatin for some fungi.

Antibody: a protein produced by plasma cells in response to a specific antigen. Antibodies bind to antigens, often resulting in the inactivation of the antigen itself or the organism to which the antigen is attached. *See also* Antigen.

Antifungal: a substance which kills or inhibits the growth of a fungus.

Antigen: a substance, especially a protein, which stimulates production of antibodies.

Antiretroviral: a substance that stops or suppresses the activity of a retrovirus (for example, AZT, ddI, ddC). HIV is a retrovirus. There are now antiretroviral drugs that suppress HIV in different ways, such as protease inhibitors and reverse transcriptase inhibitors.

Antiviral: a substance that stops or suppresses the activity of a virus (for example, acyclovir, ganciclovir, foscarnet).

ARC: (abbreviation) *see* AIDS-Related Complex.

Asymptomatic: infection without symptoms. Someone may have HIV disease without showing any symptoms.

AZT intolerant: someone who has severe side effects from taking AZT and cannot continue taking it.

bDNA assay: *see* HIV RNA

Biopsy: removal of a small amount of tissue from the patient, either surgically or with a small needle, for microscopic examination to determine if disease is present.

Blinding: in research, refers to the process of preventing patients and/or their doctors from knowing whether the patient is taking active drug or placebo. *See also* Double-blind.

Bone marrow: soft tissue in the interior of a bone where blood cells are produced.

Bronchoscopy: examination of the bronchi (lung passages) with the aid of a bronchoscope (a tube inserted into the lungs).

Candida: a white, patchy fungus which often grows in the mouth or esophagus of people with AIDS, causing pain or difficulty in swallowing. Infection with *Candida* is known as "candidiasis" or "thrush."

CD4 cell: *see* T-cell

Central nervous system (CNS): the brain and spinal cord.

Cervical Dysplasia: the development of abnormal tissue on the cervix, the outlet of the uterus, may progress to cancer.

Chemotherapy: the treatment of disease by chemical agents; usually refers to cancer treatment.

Clinical trial: a study which tests experimental medicines in human beings.

CMV: (abbreviation) *see* Cytomegalovirus.

Combination therapy (for AIDS): the use of two or more antiretroviral treatments in combination against HIV.

Community-Based Clinical Trial (CBCT): a clinical trial conducted primarily by primary-care physicians, rather than in academic research facilities

Compassionate use: an FDA program that makes certain experimental drugs available to seriously ill people when no other treatment exists or when the patient cannot tolerate other treatments.

Cryptococcal meningitis: a fungal infection caused by *Cryptococcus neoformans* that affects the three membranes (meninges) surrounding the brain and spinal cord. Symptoms include severe headache, dizziness, nausea, loss of appetite, vision disorders and mental deterioration.

Cryptosporidiosis: an opportunistic infection of the intestines caused by a protozoan parasite (*Cryptosporidium parvum*)

Cytomegalovirus (CMV): a virus that can cause aching, fever, mild sore throat, fatigue and enlarged lymph nodes. In AIDS, severe CMV infections can produce hepatitis, pneumonia, retinitis and colitis, leading in some cases to blindness, chronic diarrhea and death.

Diagnosis: determining the cause and nature of an illness

Disseminated: spread throughout the body.

Dose-ranging: drug trial in which different doses of a given drug are compared in order to determine which dose is the most effective and the least toxic.

Double-blind (double-masked): trial procedure in which neither experimental subjects nor doctors know which subjects are receiving the test drug and which are receiving a placebo or other therapy. This method is believed to promote faster and more objective results, as doctors' and patients' opinions about a test drug's efficacy might otherwise bias test results.

Efficacy: a drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed.

Encephalitis: inflammation of the brain.

Endoscopy: viewing the inside of a body cavity with a device using flexible fiber optics

Expanded access: (also called "parallel track") a procedure established by the FDA which permits the use of investigational drugs by individual physicians. The purpose of this program is to make the drug available to patients who need it, while collecting at least some limited data on efficacy and toxicity.

Experimental drug: a drug that is being tested for use as a treatment for a specific condition in a specific population.

FDA, Food and Drug Administration: The U.S. government department that approves and regulates drugs and medical devices. Pharmaceutical companies must have FDA approval to sell a new medicine.

Herpes: 1) a group of viruses including herpes simplex I (HSV I), herpes simplex II (HSV II), varicella zoster (also called shingles), Epstein-Barr virus, and cytomegalovirus. 2) a common name for blisters on the mouth or genital regions caused by herpes simplex I and II.

Histoplasmosis: a fungal disease resulting from infection with *Histoplasma capsulatum*

HIV: (abbreviation) *see* Human Immunodeficiency Virus.

HIV positive: having antibodies to the human immunodeficiency virus in the body. Implies infection with HIV.

HIV RNA tests: see "Viral Load"

Human Immunodeficiency Virus: a slow-acting retrovirus which many people believe to be the sole or foremost causative agent of AIDS and ARC.

Immune Thrombocytopenic Purpura (ITP): an autoimmune disease, in which the destruction of platelets (thrombocytes) leads to an increased susceptibility to bruising and bleeding.

Immunomodulator: a drug which alters, suppresses or strengthens the immune system.

IND: (abbreviation) *see* Investigational New Drug.

Induction: the initiation of a particular therapy

Infusion: the process of giving a substance (medication, food supplements, etc.) to a patient by injecting it into the blood stream. This procedure can either be a one-time event or continued over many hours, days or months.

Investigational New Drug (IND): an application submitted to the Food and Drug Administration for permission to test a new drug or an old drug for a new indication in humans

ITP: *see* Immune Thrombocytopenic Purpura.

Kaposi's sarcoma (KS): an abnormal proliferation of small, poorly formed blood vessels which occurs in some people with AIDS. KS lesions may first appear anywhere on the body or in the soft palate of the mouth; they may also remain hidden in the internal organs.

Lesion: a change in tissue caused by disease. A point or localized patch of a skin disease. Other words that mean about the same thing as lesion include "sore" or "spot."

Lumbar puncture (LP): insertion of a needle into the spinal column to remove spinal fluid or to inject anesthesia or medicine.

Lymphadenopathy: swollen, firm and possibly tender lymph glands. Causes may range from a temporary infection (such as the flu) to lymphoma.

Lymphoma: a malignancy (cancer) of lymphocytes, the cells that are responsible for normal immune function.

MAC (also called MAI): (abbreviation) *see Mycobacterium avium-Intracellulare* Complex.

Maintenance therapy: use of a treatment to maintain a desired effect that has already been achieved.

Malabsorption syndrome: decreased intestinal absorption resulting in loss of appetite, muscle pain, weightloss and diarrhea

Malignant: used to describe cells or tumors growing in an uncontrolled fashion, either spreading to other sites through the blood stream or invading nearby, normal tissues. By definition, cancers are always malignant, and the term "malignancy" implies a cancer.

Monoclonal antibodies: custom-made immune system pieces that are used against one specific disease-causing agent

Mycobacterium avium-Intracellulare Complex (MAC): in people with AIDS, an infection which begins in the gut or lungs and is similar to tuberculosis. Later, the infection often spreads to other organs by way of the blood stream.

Neoplasm: tissue that grows more rapidly than normal; a tumor or growth. A neoplasm that does not spread to other tissues is described as benign. A neoplasm that spreads (metastasizes) to other tissues is termed malignant, and is commonly called cancer.

Neurological disorders: disorders of the central nervous system (brain and spinal cord), such as seizures or dementia, or of the peripheral nervous system (nerves) such as a neuropathy.

Neuropathy: the name given to a group of disorders involving nerves, whose symptoms range from a tingling sensation or numbness in the toes or fingers, to paralysis. "Peripheral neuropathy" refers to nerves outside the spinal cord, usually in the feet, legs, hands or arms.

OI: (abbreviation) *see* Opportunistic infection.

Opportunistic infection (OI): illness which would not normally occur in someone whose immune system is functioning properly.

Open label trial: (also called non-masked or non-randomized trial) a drug trial in which both doctors and subjects know what drug a subject is taking (and at what dose).

p24 antibody test: a test that measures the amount of antibodies in the blood against the p24 antigen.

p24 antigen test: a test that detects a protein fragment (p24) from HIV's core in blood and other body fluids. Not an accurate measurement of viral activity.

Pancreatitis: inflammation of the pancreas which can result in severe abdominal pain. Pancreatitis can be a side effect of a drug, but can occur due to including gallstones, viral infection and excessive alcohol intake.

Parenteral: not through the mouth. Intravenous, intramuscular, and intradermal routes of administration of drugs are all parenteral

PCP: (abbreviation) *see Pneumocystis carinii* Pneumonia.

PCR (Polymerase Chain Reaction) Test: A test to measure the amount of RNA or DNA (genetic material) of a virus or other organism in the blood or tissue. PCR tests are used to test HIV viral load.

Pharmacokinetics: the study of how drugs are absorbed, processed and eliminated by the body. This helps in determining the best route of administration, dosage and dosing schedule.

Phase I clinical trials: toxicity and dose-finding clinical studies which evaluate the drug's actions in the body, its safe dosage range, how it is absorbed, distributed, metabolized and excreted from the body. These trials are usually completed within a year and involve a small number of research subjects.

Phase II clinical trials: efficacy studies which often include several hundred human volunteers. They are designed to assess the drug's effectiveness precisely and to detect major adverse reactions (side effects).

Phase III clinical trials: involve up to several thousand participants to confirm earlier findings of effectiveness and to find side effects that occur only rarely or after a long period of treatment. They may last several years.

Phase IV clinical trials: studies designed to evaluate the long-term safety and effectiveness of a drug usually carried out after licensure of the drug. Also known as "Post-Marketing" studies

Placebo: an inactive substance against which test drugs (active or "real" drugs) are compared. In placebo-controlled trials the control group takes a placebo, while the test group takes an experimental drug. Many such studies are double-blinded so that neither the patients nor their doctors know which substance the patients are receiving. Placebos are usually harmless.

Platelets (also called thrombocytes): blood cells which help the normal clotting of blood.

***Pneumocystis carinii* Pneumonia (PCP):** a type of pneumonia caused by a common parasite that grows rapidly in the lungs of people with AIDS. PCP is the leading cause of death in AIDS. Rarely, *Pneumocystis carinii* infections may occur elsewhere in the body.

PO: Oral; taken by mouth as pill or liquid.

Prodrug: a class of drug which works after being converted in the body by metabolic processes

Prophylaxis: treatment intended to prevent people from getting a disease. For example, aerosolized pentamidine and Septra® have been shown to be effective for prophylaxis against PCP.

Protease Inhibitor: an antiretroviral drug that prevents HIV from making copies of itself (replicating) by blocking an enzyme called "protease".

Protocol: detailed plan which states a clinical trial's rationale, goal, hypothesis, the drugs involved, dosage levels, methods of administration and treatment durations, as well as who may participate, their disease and its severity.

Radiation therapy: a treatment for cancer using radiation.

Randomized trial: in a randomized trial, participants are assigned by chance to receive one of the treatments being studied.

Rechallenge: to take a drug again despite previous bad side effects.

Refractory: severe disease that is resistant to treatment.

Regimen: any particular treatment plan specifying which drugs are used, in what dose, according to what schedule, and for how long

Remission: when the symptoms of a condition disappear. "Remission" is not the same as "cure," because a disease can sometimes come back after it has been in remission.

Renal disease: disease of the kidney.

Resistance: reduction in sensitivity to a particular drug.

Retinitis: inflammation of the retina, a part of the eye. In people with AIDS, retinitis is often caused by CMV or HSV infections. If left untreated, it leads in most cases to blindness.

Salvage therapy: treatment for patients who are non-responsive to or cannot tolerate other available treatments for a particular condition.

Shingles: see herpes zoster

Side effects: an unintended effect. Some side effects are unwanted, harmful or poisonous (toxic), and are called "adverse reactions."

Spinal tap: *see* Lumbar puncture.

STD: sexually transmitted disease.

Study: a general term for any of a variety of research activities involving the collection, analysis or interpretation of data.

Symptom: any condition occurring because of a disease. For example, coughing is one symptom of *Pneumocystis* pneumonia, and headaches are a symptom of cryptococcal meningitis.

Systemic: throughout the body. Sometimes applies to medications that are taken orally or parenterally that saturate the entire body

T-cells (CD4 cells): also called T4 cells or T-helper cells. The T4 cell enhances the immune response to an infection through a complex series of interactions with other types of cells.

Thrush: a *Candida* infection of the mouth and throat often found in people with HIV infection.

Toxicity: the degree to which a substance is poisonous. Clinical trials determine how much of a drug can be taken safely without having a toxic effect.

Toxoplasmosis ("toxo"): a disease caused by a parasite, *Toxoplasma gondii*, often involving the brain, eyes, heart, liver and lungs.

Vaccine: a substance that contains all or a portion of a disease-causing organism (usually "killed" by heat or chemicals) given for prevention or treatment of a disease. By stimulating production of antibodies, the vaccine helps to protect against infection by that organism.

Viral Load: the number of viral particles (usually HIV) measured in a sample of blood plasma. Viral load test results are given as number of HIV copies or equivalents (Eq) per milliliter. There are two tests to measure viral load: PCR and bDNA.

Virus: microscopic agent which requires a living cell in order to reproduce. When viruses infect cells they can cause disease, often killing the cells they infect. Important viruses include Human immunodeficiency virus (HIV), Herpes and Cytomegalovirus (CMV).

Wasting Syndrome: progressive, involuntary weight loss associated with advanced HIV infection.

White Blood Cells: part of the immune system that protects the body against foreign substances such as disease-producing microorganisms

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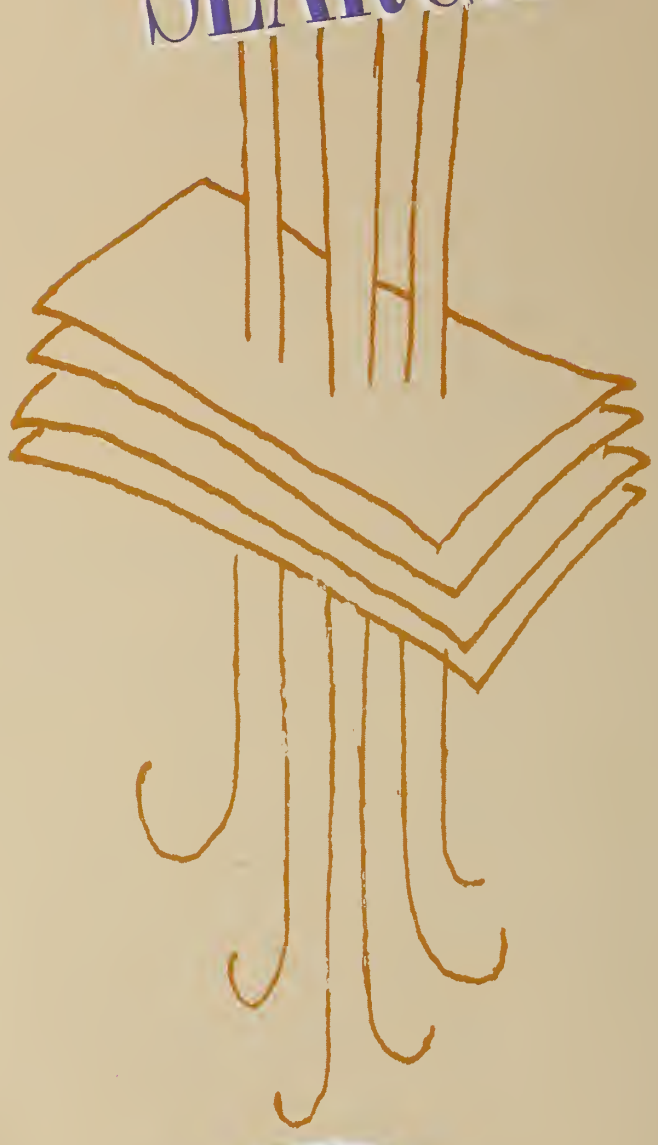

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